



US008647392B2

(12) **United States Patent**  
**Kutsko et al.**

(10) **Patent No.:** **US 8,647,392 B2**  
(45) **Date of Patent:** **\*Feb. 11, 2014**

(54) **ARTICULABLE ANCHOR**

(75) Inventors: **James Kutsko**, Carnation, WA (US);  
**Seung Yi**, Aliso Viejo, CA (US); **Clinton Lee Finger**, Bellevue, WA (US)

(73) Assignee: **Spiration, Inc.**, Redmond, WA (US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/457,346**

(22) Filed: **Apr. 26, 2012**

(65) **Prior Publication Data**

US 2012/0209308 A1 Aug. 16, 2012

**Related U.S. Application Data**

(63) Continuation of application No. 12/754,394, filed on Apr. 5, 2010, which is a continuation of application No. 11/585,415, filed on Oct. 24, 2006, now Pat. No. 7,691,151.

(60) Provisional application No. 60/787,995, filed on Mar. 31, 2006.

(51) **Int. Cl.**  
*A61F 2/06* (2013.01)  
*A61M 15/00* (2006.01)

(52) **U.S. Cl.**  
USPC ..... **623/23.65**; 623/9; 128/200.24

(58) **Field of Classification Search**  
USPC ..... 623/9, 23.64–23.65; 604/892.1  
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,832,078 A 4/1958 Williams  
2,981,254 A 4/1961 Vanderbilt  
3,320,972 A 5/1967 High et al.  
3,370,305 A 2/1968 Goott et al.

(Continued)

FOREIGN PATENT DOCUMENTS

AU 2002239759 5/2002  
CA 2308186 5/1999

(Continued)

OTHER PUBLICATIONS

U.S. Appl. No. 09/686,204, filed Oct. 10, 2000, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

(Continued)

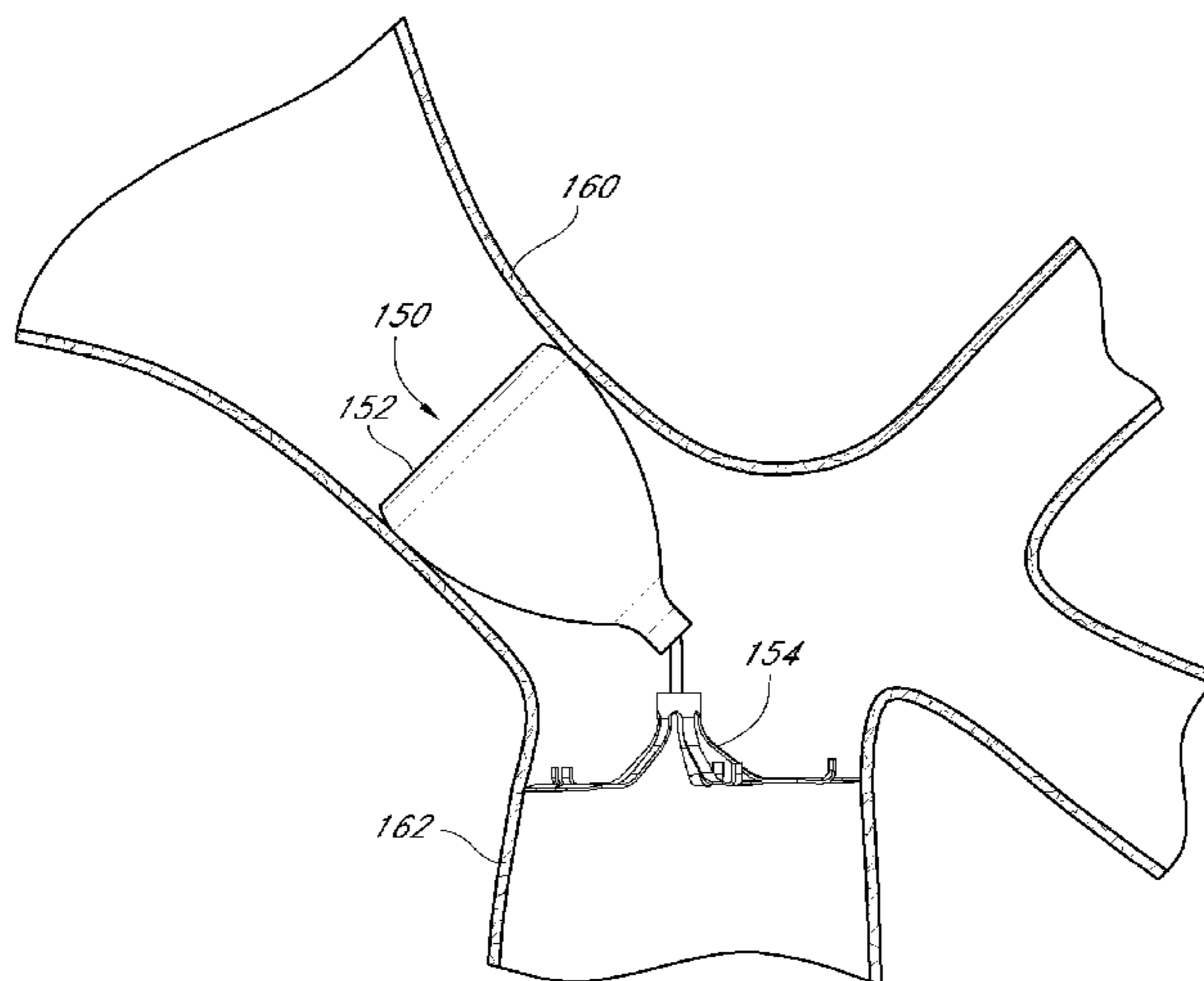
*Primary Examiner* — Suzette J Gherbi

(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear LLP

(57) **ABSTRACT**

Embodiments disclosed herein relate to devices implantable into a human lung, for example to reduce the volume of air trapped in a diseased portion of the lung to prevent inhalation while permitting expiration out of the diseased portion. In some embodiments, the device comprises a distal portion with an anchor system that may anchor the device into tissue of an air passageway wall, and the distal portion may be connected to a proximal portion via a flexible portion that permits the distal portion to articulate substantially with respect to the proximal portion, such that the distal portion and the proximal portion may be non-collinear along a longitudinal axis of the distal portion. This may facilitate implantation of the device into a non-linear air passageway.

**34 Claims, 11 Drawing Sheets**



(56)

## References Cited

## U.S. PATENT DOCUMENTS

3,445,916 A	5/1969	Schulte	5,366,478 A	11/1994	Brinkerhoff et al.
3,472,230 A	10/1969	Forgarty	5,370,657 A	12/1994	Irie
3,540,431 A	11/1970	Modin-Uddin	5,382,261 A	1/1995	Palmaz
3,617,060 A	11/1971	Iezzi	5,383,470 A	1/1995	Kolby
3,657,744 A	4/1972	Ersek	5,391,205 A	2/1995	Knight
3,671,979 A	6/1972	Moulopoulos	5,392,775 A	2/1995	Adkins, Jr. et al.
3,683,913 A	8/1972	Kurtz et al.	5,398,844 A	3/1995	Zaslavsky
3,757,783 A	9/1973	Alley	5,409,019 A	4/1995	Wilk
3,760,808 A	9/1973	Bleuer	5,409,444 A	4/1995	Kensey et al.
3,788,327 A	1/1974	Donowitz et al.	5,411,507 A	5/1995	Heckele
3,874,388 A	4/1975	King et al.	5,411,552 A	5/1995	Andersen et al.
4,014,318 A	3/1977	Dockum et al.	5,413,599 A	5/1995	Imachi et al.
4,040,428 A	8/1977	Clifford	5,415,660 A	5/1995	Campbell et al.
4,056,854 A	11/1977	Boretos et al.	5,417,226 A	5/1995	Juma
4,084,268 A	4/1978	Ionescu et al.	5,421,325 A	6/1995	Cinberg et al.
4,086,665 A	5/1978	Poirlier	5,445,626 A	8/1995	Gigante
4,212,463 A	7/1980	Repinski et al.	5,453,090 A	9/1995	Martinez et al.
4,218,782 A	8/1980	Rygg	5,459,544 A	10/1995	Emura
4,222,126 A	9/1980	Boretos et al.	5,484,444 A	1/1996	Braunschweiler et al.
4,250,873 A	2/1981	Bonnet	5,486,154 A	1/1996	Kelleher
4,301,810 A	11/1981	Belman	5,499,995 A	3/1996	Teirstein
4,302,854 A	12/1981	Runge	5,500,014 A	3/1996	Quijano et al.
4,339,831 A	7/1982	Johnson	RE35,225 E	4/1996	Herweck et al.
RE31,040 E	9/1982	Possis	5,507,754 A	4/1996	Green et al.
4,403,616 A	9/1983	King	5,507,797 A	4/1996	Suzuki
4,456,016 A	6/1984	Nowacki et al.	5,509,900 A	4/1996	Kirkman
4,512,338 A	4/1985	Balko et al.	5,514,153 A	5/1996	Bonutti et al.
4,533,137 A	8/1985	Sonne	5,549,626 A	8/1996	Miller et al.
4,569,674 A	2/1986	Phillips et al.	5,549,628 A	8/1996	Cooper et al.
4,582,058 A	4/1986	Depel et al.	5,562,608 A	10/1996	Sekins et al.
4,592,741 A	6/1986	Vincent	5,562,641 A	10/1996	Flomenblit et al.
4,727,873 A	3/1988	Mobin-Uddin	5,562,728 A	10/1996	Lazarus et al.
4,819,664 A	4/1989	Nazari	5,603,698 A	2/1997	Roberts et al.
4,822,354 A	4/1989	Elosegui	5,607,469 A	3/1997	Frey
4,830,003 A	5/1989	Wolff et al.	5,645,565 A	7/1997	Rudd et al.
4,832,680 A	5/1989	Haber et al.	5,647,857 A	7/1997	Andersen et al.
4,846,836 A	7/1989	Reich	5,660,175 A	8/1997	Dayal
4,850,999 A	7/1989	Planck	5,662,622 A	9/1997	Gore et al.
4,852,568 A	8/1989	Kensey	5,662,713 A	9/1997	Andersen et al.
4,877,025 A	10/1989	Hanson	5,669,933 A	9/1997	Simon et al.
4,908,028 A	3/1990	Colon et al.	5,676,671 A	10/1997	Inoue
4,934,999 A	6/1990	Bader	5,683,451 A	11/1997	Lenker et al.
4,936,823 A	6/1990	Colvin et al.	5,690,644 A	11/1997	Yurek et al.
4,968,294 A	11/1990	Salama	5,693,089 A	12/1997	Inoue
4,973,047 A	11/1990	Norell	5,697,968 A	12/1997	Rogers et al.
4,979,505 A	12/1990	Cox	5,702,343 A	12/1997	Alferness
4,984,581 A	1/1991	Stice	5,702,409 A	12/1997	Rayburn et al.
5,033,312 A	7/1991	Stupecky	5,725,519 A	3/1998	Penner et al.
5,038,621 A	8/1991	Stupecky	5,752,522 A	5/1998	Murphy
5,059,208 A	10/1991	Coe et al.	5,752,965 A	5/1998	Francis et al.
5,061,274 A	10/1991	Kensey	5,755,770 A	5/1998	Ravenscroft
5,078,739 A	1/1992	Martin	5,763,979 A	6/1998	Mukherjee et al.
5,092,781 A	3/1992	Casciotti et al.	5,782,896 A	7/1998	Chen et al.
5,116,360 A	5/1992	Pinchuk et al.	5,797,920 A	8/1998	Kim
5,116,564 A	5/1992	Jansen et al.	5,797,960 A	8/1998	Stevens et al.
5,123,919 A	6/1992	Sauter et al.	5,800,339 A	9/1998	Salama
5,135,488 A	8/1992	Foote et al.	5,803,078 A	9/1998	Brauner
5,151,105 A	9/1992	Kwan-Gett	5,810,837 A	9/1998	Hofmann et al.
5,158,548 A	10/1992	Lau et al.	5,817,101 A	10/1998	Fiedler
5,161,524 A	11/1992	Evans	2,479,805 A	11/1998	Sabaratnam
5,171,299 A	12/1992	Heitzmann et al.	5,830,217 A	11/1998	Ryan
5,197,980 A	3/1993	Gorshkov et al.	5,833,694 A	11/1998	Poncet
5,255,687 A	10/1993	McKenna	5,840,081 A	11/1998	Andersen et al.
5,275,169 A	1/1994	Afromowitz et al.	5,851,232 A	12/1998	Lois
5,281,229 A	1/1994	Neward	5,855,587 A	1/1999	Hyon
5,283,063 A	2/1994	Freeman	5,855,597 A	1/1999	Jayaraman
5,300,050 A	4/1994	Everett, Jr. et al.	5,855,601 A	1/1999	Bessler et al.
5,304,199 A	4/1994	Myers	5,876,434 A	3/1999	Flomenblit et al.
5,306,234 A	4/1994	Johnson	5,876,445 A	3/1999	Andersen et al.
5,314,473 A	5/1994	Godin	5,911,756 A	6/1999	Debry
5,339,805 A	8/1994	Parker	5,925,063 A	7/1999	Khosravi
5,342,298 A	8/1994	Michaels	5,944,738 A	8/1999	Amplatz et al.
5,352,240 A	10/1994	Ross	5,947,997 A	9/1999	Pavcnik et al.
5,353,470 A	10/1994	Bartlett	5,954,636 A	9/1999	Schwartz et al.
5,358,518 A	10/1994	Camilli	5,954,766 A	9/1999	Zadno-Azizi et al.
			5,957,949 A	9/1999	Leonhardt et al.
			5,957,978 A	9/1999	Blom
			5,972,009 A	10/1999	Fortier et al.
			5,976,158 A	11/1999	Adams et al.



(56)

## References Cited

## U.S. PATENT DOCUMENTS

5,976,174	A	11/1999	Ruiz	6,440,164	B1	8/2002	DiMatteo et al.
5,984,965	A	11/1999	Knapp et al.	6,447,530	B1	9/2002	Ostrovsky et al.
5,989,234	A	11/1999	Valerio et al.	6,454,754	B1	9/2002	Frank
6,003,517	A	12/1999	Sheffield et al.	6,458,076	B1	10/2002	Pruitt
6,007,575	A	12/1999	Samuels	6,458,153	B1	10/2002	Bailey et al.
6,009,614	A	1/2000	Morales	6,471,718	B1	10/2002	Stahle et al.
6,010,511	A	1/2000	Murphy	6,471,979	B2	10/2002	New et al.
6,010,525	A	1/2000	Bonutti et al.	6,485,407	B2	11/2002	Alferness et al.
6,020,380	A	2/2000	Killian	6,488,673	B1	12/2002	Laufer
6,027,525	A	2/2000	Suh et al.	6,491,706	B1	12/2002	Alferness et al.
6,045,560	A	4/2000	McKean et al.	6,493,589	B1	12/2002	Medhkour et al.
6,051,022	A	4/2000	Cai et al.	6,503,272	B2	1/2003	Duerig et al.
6,068,635	A	5/2000	Gianotti	6,510,846	B1	1/2003	O'Rourke
6,068,638	A	5/2000	Makower	6,514,290	B1	2/2003	Loomas
6,077,214	A	6/2000	Schweich et al.	6,527,761	B1	3/2003	Soltész et al.
6,077,291	A	6/2000	Das	6,540,782	B1	4/2003	Snyders
6,079,413	A	6/2000	Baran	6,544,192	B2	4/2003	Starr et al.
6,083,141	A	7/2000	Hougen	6,544,291	B2	4/2003	Taylor
6,083,255	A	7/2000	Laufer et al.	6,551,303	B1	4/2003	Van Tassel et al.
6,096,027	A	8/2000	Layne	6,558,429	B2	5/2003	Taylor
6,099,551	A	8/2000	Gabbay	6,568,387	B2	5/2003	Davenport et al.
6,123,663	A	9/2000	Rebuffat	6,569,166	B2	5/2003	Gonzalez
6,132,458	A	10/2000	Stahle et al.	6,585,639	B1	7/2003	Kotmel et al.
6,135,729	A	10/2000	Aber	6,589,256	B2	7/2003	Forber
6,135,991	A	10/2000	Muni et al.	6,592,594	B2	7/2003	Rimbaugh et al.
6,141,855	A	11/2000	Morales	6,599,311	B1	7/2003	Biggs et al.
6,146,357	A	11/2000	Addis	6,600,307	B2	7/2003	Turski
6,149,664	A	11/2000	Kurz	6,610,043	B1	8/2003	Ingenito
6,162,245	A	12/2000	Jayaraman	6,629,951	B2	10/2003	Laufer et al.
6,165,179	A	12/2000	Cathcart et al.	6,632,243	B1	10/2003	Zadno-Azizi et al.
6,168,614	B1	1/2001	Andersen et al.	6,634,363	B1	10/2003	Danek et al.
6,168,617	B1	1/2001	Blaeser et al.	6,638,285	B2	10/2003	Gabbay
6,174,307	B1	1/2001	Daniel et al.	6,648,897	B2	11/2003	Hamilton
6,174,323	B1	1/2001	Biggs	6,669,724	B2	12/2003	Park et al.
6,183,520	B1	2/2001	Pintauro et al.	6,673,070	B2	1/2004	Edwards et al.
6,193,748	B1	2/2001	Thompson et al.	6,679,264	B1	1/2004	Deem et al.
6,200,333	B1	3/2001	Laufer	6,682,250	B2	1/2004	Banks
6,203,551	B1	3/2001	Wu	6,682,520	B2	1/2004	Ingenito
6,206,918	B1	3/2001	Campbell et al.	6,694,979	B2	2/2004	Deem et al.
6,210,338	B1	4/2001	Afremov et al.	6,709,401	B2	3/2004	Perkins et al.
6,231,587	B1	5/2001	Makower	6,712,812	B2	3/2004	Roschak et al.
6,231,589	B1	5/2001	Wessman et al.	6,716,208	B2	4/2004	Humes
6,234,996	B1	5/2001	Bagaoisan et al.	6,722,360	B2	4/2004	Doshi
6,238,334	B1	5/2001	Easterbrook, III et al.	6,743,259	B2	6/2004	Ginn
6,240,615	B1	6/2001	Kimes et al.	6,746,686	B2	6/2004	Hughes et al.
6,241,654	B1	6/2001	Alferness	6,749,606	B2	6/2004	Keast et al.
6,241,678	B1	6/2001	Afremov et al.	6,840,952	B2	1/2005	Saker et al.
6,241,758	B1	6/2001	Cox	6,849,049	B2	2/2005	Starr et al.
6,242,472	B1	6/2001	Sekins et al.	6,849,084	B2	2/2005	Rabkin et al.
6,245,102	B1	6/2001	Jayaraman	6,860,847	B2	3/2005	Alferness et al.
6,258,100	B1	7/2001	Alferness et al.	6,887,256	B2	5/2005	Gilson
6,264,700	B1	7/2001	Kilcoyne et al.	6,904,909	B2	6/2005	Andreas et al.
6,267,775	B1	7/2001	Clerc et al.	6,911,028	B2	6/2005	Shaddock
6,270,527	B1	8/2001	Campbell et al.	6,929,637	B2	8/2005	Gonzalez et al.
6,287,290	B1	9/2001	Perkins et al.	6,941,950	B2	9/2005	Wilson et al.
6,287,334	B1	9/2001	Moll et al.	6,951,571	B1	10/2005	Srivastava
6,293,951	B1	9/2001	Alferness et al.	6,955,675	B2	10/2005	Jain
6,299,604	B1	10/2001	Ragheb et al.	6,958,076	B2	10/2005	Acosta et al.
6,302,893	B1	10/2001	Limon et al.	6,989,027	B2	1/2006	Allen et al.
6,312,407	B1	11/2001	Zadno-Azizi et al.	6,997,951	B2	2/2006	Solem et al.
6,325,777	B1	12/2001	Zadno-Azizi et al.	7,011,094	B2	3/2006	Rapacki et al.
6,325,778	B1	12/2001	Zadno-Azizi et al.	7,100,616	B2	9/2006	Springmeyer
6,327,772	B1	12/2001	Zadno-Azizi et al.	7,141,046	B2	11/2006	Perkins et al.
6,328,689	B1	12/2001	Gonzalez et al.	7,169,140	B1	1/2007	Kume
6,331,183	B1	12/2001	Suon	7,175,644	B2	2/2007	Cooper et al.
6,338,728	B1	1/2002	Valerio et al.	7,207,946	B2	4/2007	Sirokman
6,342,062	B1	1/2002	Suon et al.	7,252,086	B2	8/2007	Tanaka
6,350,278	B1	2/2002	Lenker et al.	7,278,430	B2	10/2007	Kumar
6,355,014	B1	3/2002	Zadno-Azizi et al.	7,357,795	B2	4/2008	Kaji et al.
6,398,775	B1	6/2002	Perkins et al.	7,412,977	B2	8/2008	Fields et al.
6,402,754	B1	6/2002	Gonzalez	7,434,578	B2	10/2008	Dillard et al.
6,416,554	B1	7/2002	Alferness et al.	7,476,203	B2	1/2009	DeVore et al.
6,425,916	B1	7/2002	Garrison et al.	7,530,995	B2	5/2009	Quijano et al.
6,428,561	B1	8/2002	Johansson-Ruden et al.	7,533,671	B2	5/2009	Gonzalez et al.
6,439,233	B1	8/2002	Geertsema	7,691,151	B2	4/2010	Kutsko
				7,704,268	B2	4/2010	Chanduszko
				7,757,692	B2	7/2010	Alferness et al.
				7,798,974	B2	9/2010	Sirokman
				7,842,061	B2	11/2010	Dillard et al.



(56)

References Cited

FOREIGN PATENT DOCUMENTS

U.S. PATENT DOCUMENTS			FOREIGN PATENT DOCUMENTS			
			CA	2375752	1/2001	
			CA	2401331	3/2001	
			CA	2408923	11/2001	
7,854,228	B2	12/2010	Wilson et al.	CN	101868199	10/2010
7,862,500	B2	1/2011	Khairkhahan et al.	DE	100 04 979	8/2000
7,875,048	B2	1/2011	Dillard et al.	EP	0 665 029	8/1995
7,887,585	B2	2/2011	Gonzalez et al.	EP	0 743 071	11/1996
7,896,887	B2	3/2011	Rimbaugh et al.	EP	1 151 729	11/2001
8,177,809	B2	5/2012	Mavani et al.	EP	1 157 663	11/2001
8,192,478	B2	6/2012	Khairkhahan et al.	EP	1 206 276	5/2002
2001/0010017	A1	7/2001	Letac et al.	EP	1 198 269	10/2009
2002/0002401	A1	1/2002	McGuckin, Jr. et al.	EP	03 716 212	12/2010
2002/0077564	A1	6/2002	Campbell et al.	GB	2 082 071	3/1982
2002/0077593	A1	6/2002	Perkins et al.	GB	2 324 729	11/1998
2002/0077696	A1	6/2002	Zadno-Azizi et al.	GB	2 348 138	9/2000
2002/0095209	A1	7/2002	Zadno-Azizi et al.	JP	58-163332	9/1983
2002/0112729	A1	8/2002	DeVore et al.	JP	60-10740	1/1994
2002/0147462	A1	10/2002	Mair et al.	JP	2003-503162	1/2003
2003/0018327	A1	1/2003	Truckai et al.	JP	2004-535887	12/2004
2003/0050648	A1	3/2003	Alferness et al.	JP	2005-527297	9/2005
2003/0051733	A1	3/2003	Kotmel et al.	JP	3742010	11/2005
2003/0055331	A1	3/2003	Kotmel et al.	JP	4387803 B2	10/2009
2003/0125763	A1	7/2003	McInnes	JP	2011-500171	1/2011
2003/0127090	A1	7/2003	Gifford et al.	RU	2140211	10/1999
2003/0154988	A1	8/2003	DeVore	SU	852321	8/1981
2003/0181922	A1	9/2003	Alferness	SU	1371700	2/1988
2003/0183235	A1	10/2003	Rimbaugh et al.	SU	1593651	9/1990
2003/0195385	A1	10/2003	De Vore	WO	WO 88/09683	12/1988
2003/0212412	A1	11/2003	Dillard et al.	WO	WO 94/26175	11/1994
2003/0216769	A1	11/2003	Dillard et al.	WO	WO 95/32018	11/1995
2003/0225445	A1	12/2003	Derus et al.	WO	WO 96/34582	11/1996
2004/0010209	A1	1/2004	Sirokman	WO	WO 96/37167	11/1996
2004/0039250	A1	2/2004	Tholfson et al.	WO	WO 97/09932	3/1997
2004/0059263	A1	3/2004	DeVore	WO	WO 97/13471	4/1997
2004/0194780	A1	10/2004	Doshi	WO	WO 97/27893	8/1997
2004/0206349	A1	10/2004	Alferness et al.	WO	WO 97/42871	11/1997
2004/0210248	A1	10/2004	Gordon et al.	WO	WO 97/44085	11/1997
2004/0211412	A1	10/2004	Alferness et al.	WO	WO 98/00840	1/1998
2004/0243140	A1	12/2004	Alferness et al.	WO	WO 98/01084	1/1998
2005/0033310	A1	2/2005	Alferness et al.	WO	WO 98/19633	5/1998
2005/0033344	A1	2/2005	Dillard et al.	WO	WO 98/39047	9/1998
2005/0096721	A1	5/2005	Mangin et al.	WO	WO 98/44854	10/1998
2005/0137611	A1	6/2005	Escudero et al.	WO	WO 98/48706	11/1998
2005/0145253	A1	7/2005	Wilson et al.	WO	WO 99/01076	1/1999
2005/0222580	A1	10/2005	Gifford, III et al.	WO	WO 99/13801	3/1999
2005/0267323	A1	12/2005	Dorros et al.	WO	WO 99/26692	6/1999
2006/0032497	A1	2/2006	Doshi	WO	WO 99/32040	7/1999
2006/0074382	A1	4/2006	Gonzalez et al.	WO	WO 99/42059	8/1999
2006/0200076	A1	9/2006	Gonzalez et al.	WO	WO 99/42161	8/1999
2006/0206147	A1	9/2006	DeVore et al.	WO	WO 99/59503	11/1999
2006/0235432	A1	10/2006	DeVore	WO	WO 99/64109	12/1999
2006/0235467	A1	10/2006	DeVore	WO	WO 00/18329	4/2000
2006/0241745	A1	10/2006	Solem et al.	WO	WO 00/27292 A	5/2000
2006/0249164	A1	11/2006	Springmeyer	WO	WO 00/42950	7/2000
2006/0270940	A1	11/2006	Tsukashima et al.	WO	WO 00/51500 A	9/2000
2007/0221230	A1	9/2007	Thompson et al.	WO	WO 00/51510	9/2000
2007/0225747	A1	9/2007	Perkins et al.	WO	WO 00/62699	10/2000
2008/0015627	A1	1/2008	DeVore	WO	WO 00/78386	12/2000
2008/0119866	A1	5/2008	Alferness	WO	WO 00/78407	12/2000
2008/0132989	A1	6/2008	Snow et al.	WO	WO 01/02042	1/2001
2009/0099530	A1	4/2009	Adams et al.	WO	WO 01/03641	1/2001
2009/0292262	A1	11/2009	Adams et al.	WO	WO 01/03642	1/2001
2010/0256714	A1	10/2010	Springmeyer	WO	WO 01/03642	1/2001
2010/0262071	A1*	10/2010	Kutsko et al. .... 604/30	WO	WO 01/05334	1/2001
2011/0054632	A1	3/2011	Alferness	WO	WO 01/05334	1/2001
2011/0079221	A1	4/2011	Dillard	WO	WO 01/10313	2/2001
2011/0196295	A1	8/2011	Gonzalez	WO	WO 01/10313	2/2001
2011/0201956	A1	8/2011	Alferness	WO	WO 01/10314	2/2001
2011/0208228	A1	8/2011	Gonzalez	WO	WO 01/12104	2/2001
2011/0283998	A1	11/2011	Alferness	WO	WO 01/13839	3/2001
2012/0016376	A1	1/2012	Adams	WO	WO 01/13908	3/2001
2012/0073126	A1	3/2012	Adams	WO	WO 01/13908	3/2001
2012/0101428	A1	4/2012	Springmeyer	WO	WO 01/28433	4/2001
2012/0165856	A1	6/2012	Alferness	WO	WO 01/30266	5/2001
				WO	WO 01/30268	5/2001
				WO	WO 01/37897	5/2001
				WO	WO 01/45590	6/2001
				WO	WO 01/49213	7/2001
				WO	WO 01/52775	7/2001
				WO	WO 01/54585	8/2001
				WO	WO 01/54625	8/2001



(56)

**References Cited**

## FOREIGN PATENT DOCUMENTS

WO	WO 01/54685	8/2001
WO	WO 01/66190	9/2001
WO	WO 01/70114	9/2001
WO	WO 01/74271	10/2001
WO	WO 01/87170	11/2001
WO	WO 01/89366	11/2001
WO	WO 01/95786	12/2001
WO	WO 02/05884	1/2002
WO	WO 02/22072	3/2002
WO	WO 02/32333	4/2002
WO	WO 02/34322	5/2002
WO	WO 02/38038	5/2002
WO	WO 02/47575	6/2002
WO	WO 02/056794	7/2002
WO	WO 02/064045	8/2002
WO	WO 02/064190	8/2002
WO	WO 02/069823	9/2002
WO	WO 02/094087	11/2002
WO	WO 01/95786	12/2002
WO	WO 03/022124	3/2003
WO	WO 03/030975	4/2003
WO	WO 03/003946	5/2003
WO	WO 03/034927	5/2003
WO	WO 03/041779	5/2003
WO	WO 03/047468	6/2003
WO	WO 03/078579	9/2003
WO	WO 03/088820	10/2003
WO	WO 03/094996	11/2003
WO	WO 03/099164	12/2003
WO	WO 2004/010845	5/2004
WO	WO 2004/080347	9/2004
WO	WO 2005/013835	2/2005
WO	WO 2006/034166	3/2006
WO	WO 2007/123690	11/2007
WO	WO 2009/049261	4/2009
WO	WO 2009/135070	11/2009
WO	WO 2010/118056	10/2010

## OTHER PUBLICATIONS

U.S. Appl. No. 09/379,972, filed Aug. 24, 1999, Pub. No. 2010/0256714, published Oct. 7, 2010 and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/052,875, filed Oct. 25, 2001, Pub. No. 2003/0083671, published May 1, 2003, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 09/881,862, filed Jun. 14, 2001, Pub. No. 2001/0052344, published Dec. 20, 2001 and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/317,667, filed Dec. 11, 2002, Pub. No. 2003/0158515, published Aug. 21, 2003, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/409,785, filed Apr. 8, 2003, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/259,007, filed Sep. 26, 2002, Pub. No. 2003/0212337, published Nov. 13, 2003, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/744,577, filed Dec. 22, 2003, Pub. No. 2004/0167636, published Aug. 26, 2004, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 11/260,012, filed Oct. 26, 2005, Pub. No. 2006/0155217, published Jul. 13, 2006, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/745,401, filed Dec. 22, 2003, Pub. No. 2005/0137714, published Jun. 23, 2005, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 11/585,415, filed Oct. 24, 2006, Pub. No. 2007/0232992, published Oct. 4, 2007, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 12/248,287, filed Apr. 22, 2009, Pub. No. 2009/0205667, published Aug. 20, 2009, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 11/738,412, filed Apr. 20, 2007, Pub. No. 2007/0250022, published Oct. 25, 2007, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/746,981, filed Dec. 23, 2003, Pub. No. 2004/0143282, published Jul. 22, 2004, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/933,778, filed Sep. 3, 2004, Pub. No. 2005/0033344, published Feb. 10, 2005, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 12/398,122, filed Mar. 4, 2009, Pub. No. 2009/0182369, published Jul. 16, 2009, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/733,710, filed Apr. 10, 2007, Pub. No. 2007/0185531, published Aug. 9, 2007, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/150,547, filed May 17, 2002, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/178,073, filed Jun. 21, 2001, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/081,712, filed Feb. 21, 2002, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 09/951,105, filed Sep. 11, 2001, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/178,073, filed Jun. 21, 2002, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/103,487, filed Mar. 20, 2002, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/148,929, filed Apr. 17, 2003, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/124,790, filed Apr. 16, 2002, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/143,353, filed May 9, 2002, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/196,513, filed Jul. 15, 2002, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.



(56)

**References Cited**

## OTHER PUBLICATIONS

U.S. Appl. No. 10/254,392, filed Sep. 24, 2002, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/827,384, filed Apr. 19, 2004, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/847,554, filed May 17, 2004, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/387,963, filed Mar. 12, 2003, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/847,427, filed May 17, 2004, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/48,041, filed May 18, 2004, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/848,571, filed Feb. 10, 2005, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 10/178,640, filed Jul. 11, 2005, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 11/204,383, filed Aug. 15, 2005, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 11/417,738, filed May 3, 2006, Issued as 7,042,931 on May 17, 2011, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 11/418,541, filed May 3, 2006, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 11/417,553, filed May 3, 2006, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 11/416,337, filed May 2, 2006, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 11/417,944, filed May 3, 2006, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 11/178,130, filed Jul. 20, 2007, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 11/880,090, filed Jul. 19, 2007, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 12/249,243, filed Oct. 10, 2008, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 12/422,179, filed Apr. 10, 2009, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 12/721,426, filed Mar. 10, 2010, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 12/754,394, filed Apr. 5, 2010, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 12/828,629, filed Jul. 1, 2010, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 12/968,771, filed Dec. 15, 2010, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 13/073,443, filed Mar. 28, 2011, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 13/198,546, filed Aug. 4, 2011, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 13/243,512, filed Sep. 23, 2011, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 12/913,257, filed Oct. 27, 2010, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 13/005,444, filed Jan. 12, 2011, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 13/312,588, filed Dec. 6, 2011, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 13/286,995, filed Nov. 1, 2011, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

U.S. Appl. No. 13/415,616, filed Mar. 8, 2012, and its ongoing prosecution history including without limitation Office Actions, Amendments, Remarks, and any other potentially relevant documents.

Amendment mailed Mar. 3, 2004 in response to Office Action dated Oct. 3, 2003 in the related copending U.S. Appl. No. 09/951,105.

Andre A. Kulisz, Autocath 100 -Nonsurgical, Intraurethral Bladder Control Device for Urinary Incontinent and Urinary Retentive Women—Another Dr. Kulisz's Development, <http://www.kulisz.com/autocath.htm>, 2003, 3 pp.

Chest Drains, from [webmaster@atroi.ed/cp](mailto:webmaster@atroi.ed/cp), from website Mar. 21, 2002; pp. 1-3.

Chest Drains, from [webmaster@surgical-tutor.org.uk](mailto:webmaster@surgical-tutor.org.uk); from Website on Mar. 21, 2002; pp. 1-3.

Dillard et al., "Evaluation of a Novel Intra-bronchial Valve Device to Produce Lung Volume Reduction," Poster show at conference in Jun. 2002.

EDO Ceramics Products and Services, from [webmaster@edocorp.com](mailto:webmaster@edocorp.com); from website on Mar. 21, 2002; pp. 1,2.

Ellis, James H., Balloon Catheter Occlusion of Bronchopleural Fistulae, May 7, 1981, *AJR*: 138, Jan. 1982, p. 157-159.

English Translation of Chinese First Office Action for Chinese Application No. 201110022562.2, issued on Sep. 28, 2012 in 12 pages.

EWS Endobronchial Watanabe Spigots, Novatech, edited Apr. 17, 2002.

Exploring Chest Drain Options; from [webmaster google.com](http://webmaster.google.com); RNWeb: Continuing Education; from website on Mar. 21, 2002; pp. 1-6.

Harris et al., "The Experimental Production in Dogs of Emphysema with Associated Asthmatic Syndrome by Means of an Intratracheal Ball Valve;" *J Exp Med* 30:1919; 75-88.



(56)

**References Cited**

## OTHER PUBLICATIONS

Horiuchi et al: Three Cases of Intractable Pneumothorax Treated Successfully by Bronchial Embolization using Silicon; JJSB, 2001. pp. 25-30.

Inaspettato: Endoscopic Treatment of Bronchopleural Fistulas Using N-butyl-2-cyanoacrylate; Surgical Laparoscopy & Endoscopy; vol. 4 No. 1, pp. 62-64, 1994.

Jones et al: Closure of a Benign Broncho-Oesophageal Fistula by Endoscopic Injection of Bovine Collagen, Cyanoacrylate Glue and Gelfoam; 1996, pp. 53-55 Aust. N.Z. J. Surg.

Lewis et al, "Pulmonary Interstitial Emphysema: Selective Bronchial Occlusion with a Swan-Ganz Catheter." Archives of Disease in Childhood, 63:1988, 313-315.

marco: Bubble Detector, from webmaster@marco.de, from Website on Mar. 21, 2002; pp. 1-3.

Matthew et al. "Selective Bronchial Obstruction for Treatment of Bullous Interstitial Emphysema," J. of Ped. 96:1980, 475-477.

Oasis Dry Suction Chest Drains; Instructions for Use; Atrium Medical Corporation, Hudson New Hampshire, on Mar. 27, 2002, pp. 1-4.

Okada et al: Emergent Bronchofiberoptic Bronchial Occlusion for Intractable Pneumothorax with Severe Emphysema; The Japanese Journal of Thoracic and Cardiovascular Surgery, 1998. pp. 1078-1081.

Puhakka et al., "Acute Bronchial Obstruction: An Experimental Rabbit Model Study." Int. J. of Pediatric Otorhinolaryngology. 18:1989, 107-118.

SIII Control and Display Modules; from webmaster@stoeckert.de; from website on Mar. 21, 2002, pp. 15.

Snider et al., "The Definition of Emphysema: Report of the National Heart Lung and Blood Institute, Division of Lung Diseases Workshop", Am. Ev. Respir. Dis., 132:182-185, 1985.

Tube Thoracostomy; from webmaster@merck.com/pubs/manual; from Website Mar. 21, 2003, pp. 1,2.

Understanding Chest Drainage; from webmaster@nursingceu.com; from website on Mar. 21, 2002; pp. 1-15.

Watanabe et al: Bronchial Embolization Using Dental Impression Material in a Case of Pyelo-bronchial Fistula with Candida Fungemia; 1991. Journal of the Japan Society for Bronchology, pp. 607-610.

European Supplemental Search Report in European Appln. No. 00969008.2, dated Feb. 26, 2004, 5 pp.

International Search Report in International application No. PCT/US00/40701, mailed Jan. 25, 2001, 3 pp.

Canadian Office Action dated Apr. 28, 2009 for Canadian Application No. 2,459,702.

Canadian Office Action dated Dec. 14, 2010 for Canadian Application No. 2,459,702.

Canadian Office Action dated Mar. 9, 2010 for Canadian Application No. 2,459,702.

European Search Report in European Appln. No. 02759335.9, dated Jan. 31, 2007.

International Search Report in International application No. PCT/US02/25555, mailed Mar. 19, 2003, 4 pp.

Extended European Search Report for EP 08 0205468, dated Jul. 28, 2009.

European Examination Report dated Apr. 14, 2010 for EP Application No. 03 71 0804.

European Supplemental Search Report dated Nov. 9, 2009 for EP Application No. 03 71 0804.

Australian Office Action of Oct. 29, 2007, Application No. 2003219927.

Canadian Office Action of Apr. 28, 2009, Application No. 2,479,805.

European Notice re Amendment of Application Documents of Jun. 17, 2009, Application No. 03 716 212.0-1265.

European Supplemental Search Report of Feb. 28, 2008, Application No. 03 716 212.0-1265.

European Office Action of Dec. 23, 2008, Application No. 03 716 212.0-1265.

Japanese Office Action re JP Application No. JP 2009-503031, dated Mar. 2, 2012, and English translation in 9 pages.

Notice of Reasons for Rejection re JP Application No. JP 2009-503031, mailed on Jul. 10, 2012 in six pages.

Japanese Office Action of Feb. 3, 2009, Application No. 2003-57779.

International Search Report of Jul. 7, 2003, Application No. PCT/US03/05968.

International Search Report dated Oct. 1, 2003 re PCT Application No. PCT/US2003/14868.

PCT Search Report and Written Opinion from corresponding PCT Application No. PCT/US2004/007721.

PCT Search Report and Written Opinion from corresponding PCT Application No. PCT/US2004/007721 dated Mar. 12, 2004.

Chinese Office Action dated Jun. 4, 2010 re CN Application No. 200780019455.6.

Japanese Office Action dated Mar. 6, 2012, JP Application No. 2009-503031 w/translation.

Japanese Office Action dated Jul. 2, 2012, JP Application No. 2009-503031 w/translation.

PCT International Search Report from corresponding PCT Application No. PCT/US2007/007923, dated May 20, 2008 in 2 pages.

PCT Preliminary and Written Report from corresponding PCT Application No. PCT/US2007/007923, dated Sep. 30, 2008 in 7 pages.

Russian Office Action, for App. No. 2008139081/14(050381), dated Nov. 24, 2010.

International Preliminary Report on Patentability for Application No. PCT/US2010/030131, dated Mar. 18, 2011.

International Report on Patentability dated Dec. 23, 2009 re PCT/US2008/079650..

International Search Report and Written Opinion for Application No. PCT/US2010/030131, dated Jun. 18, 2010.

International Search Report dated Jan. 30, 2009 re PCT/US2008/079650.

International Search Report and Written Opinion for Application No. PCT/US2004/025458, mailed Nov. 30, 2004.

European Office Action on May 6, 2011, Application No. 09739872.1.

\* cited by examiner

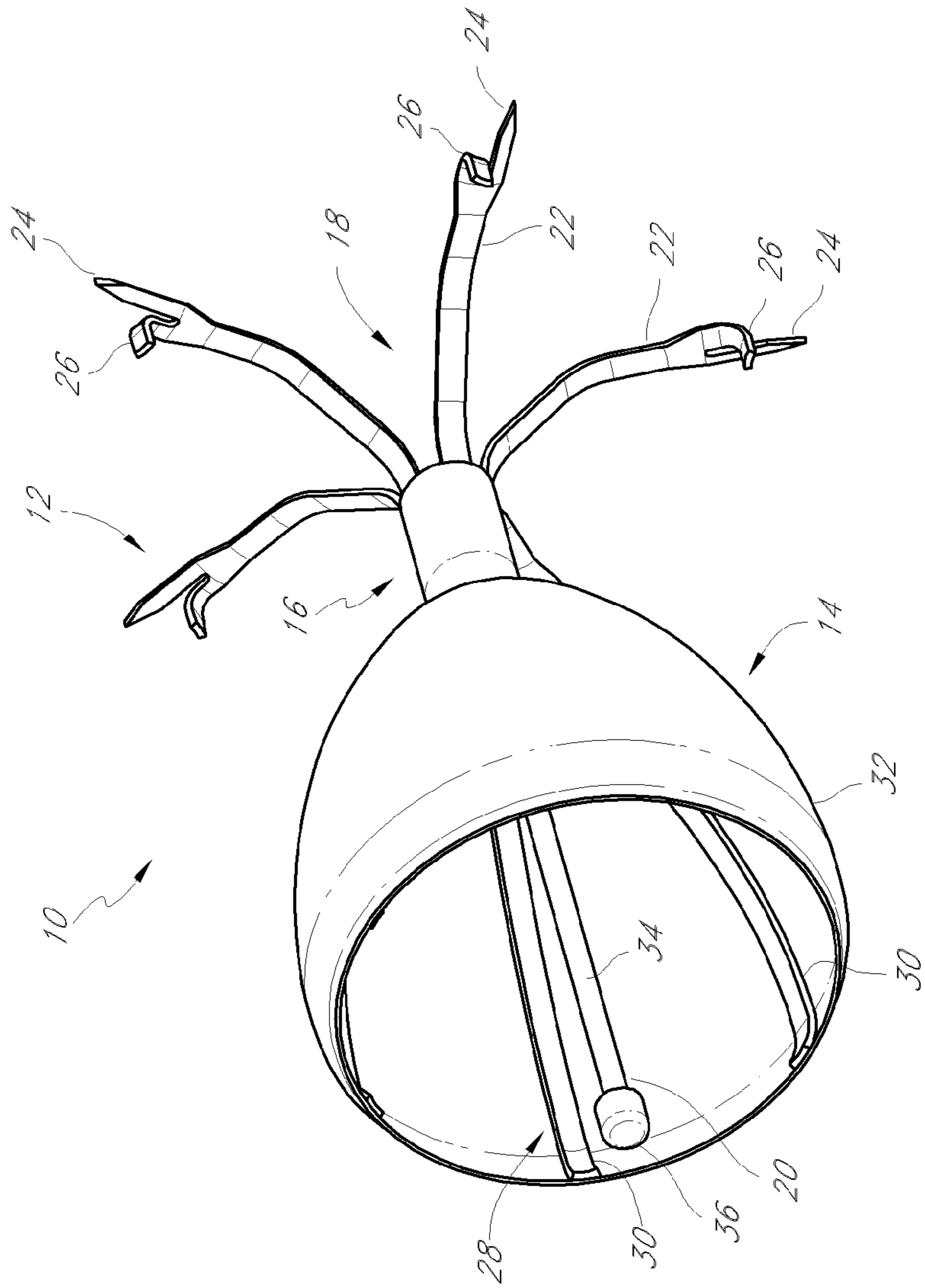


FIG. 1



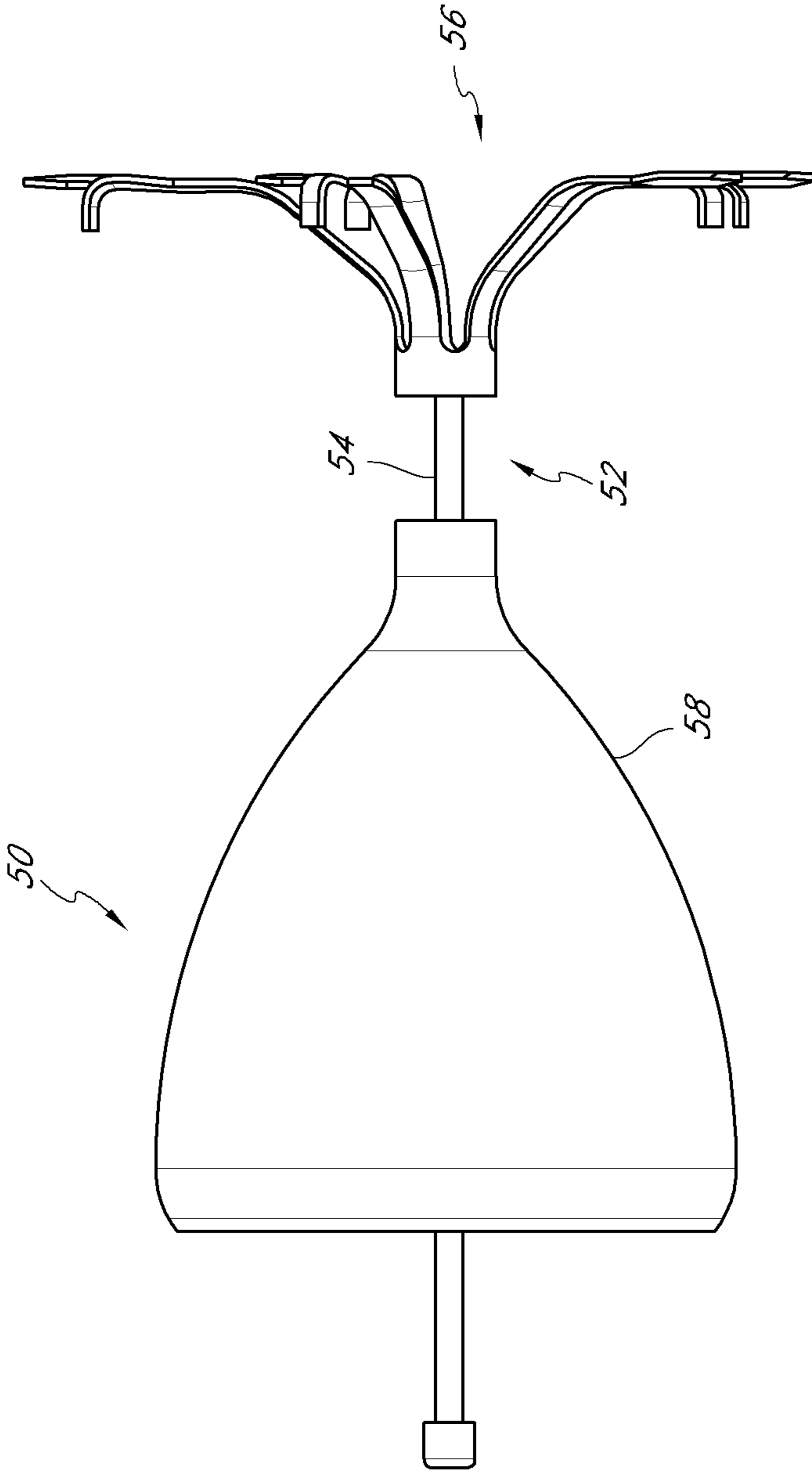


FIG. 2



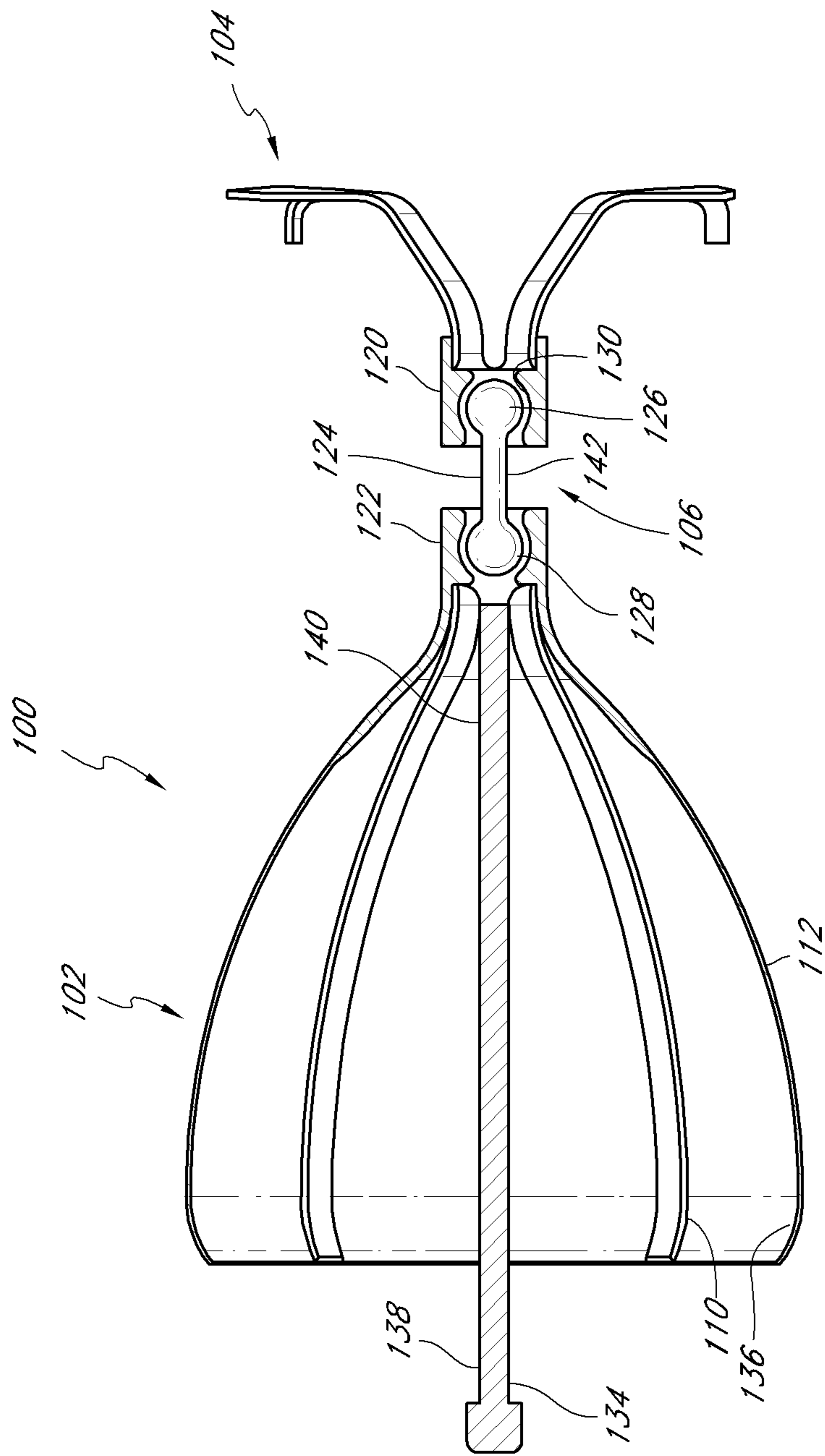


FIG. 3



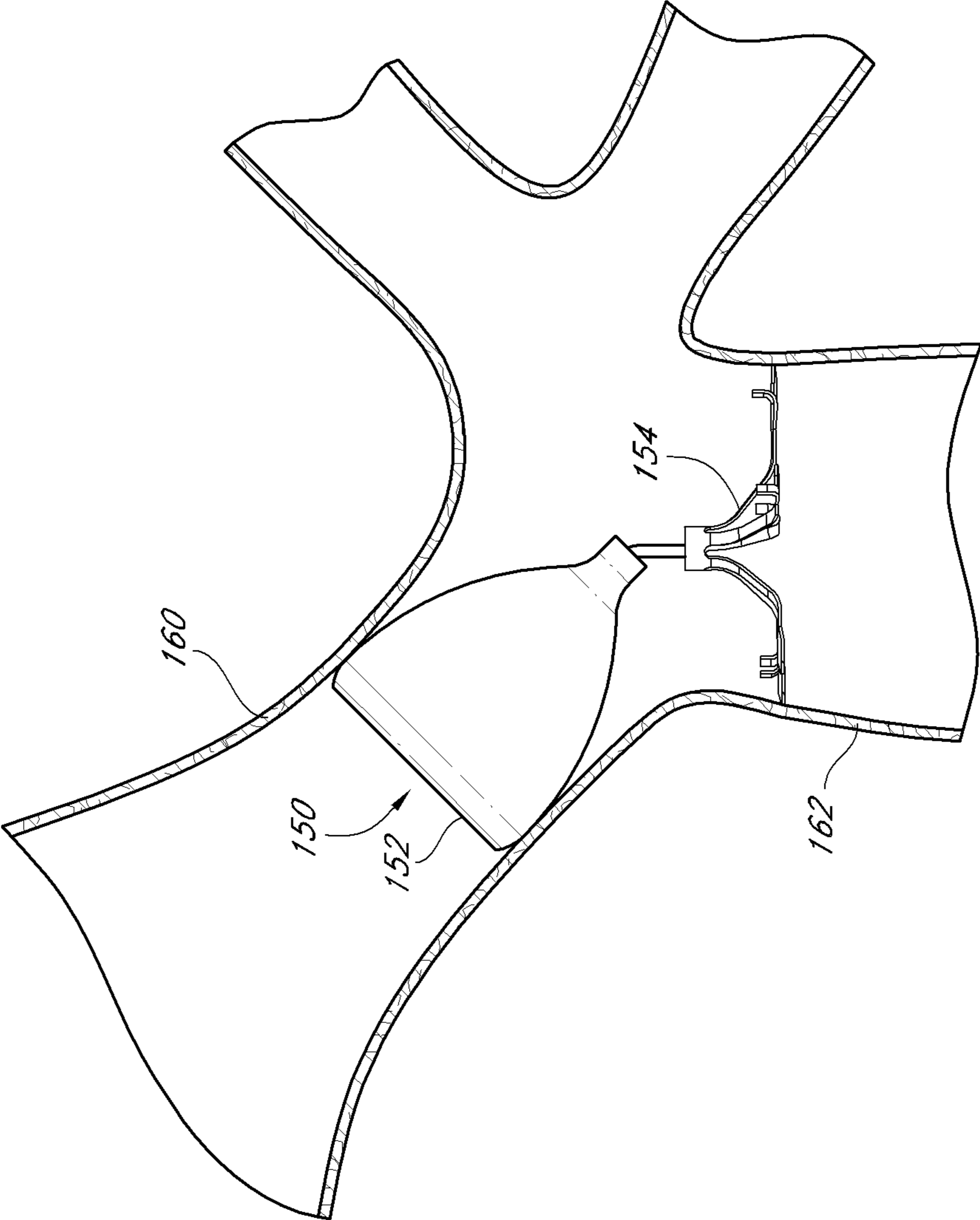


FIG. 4



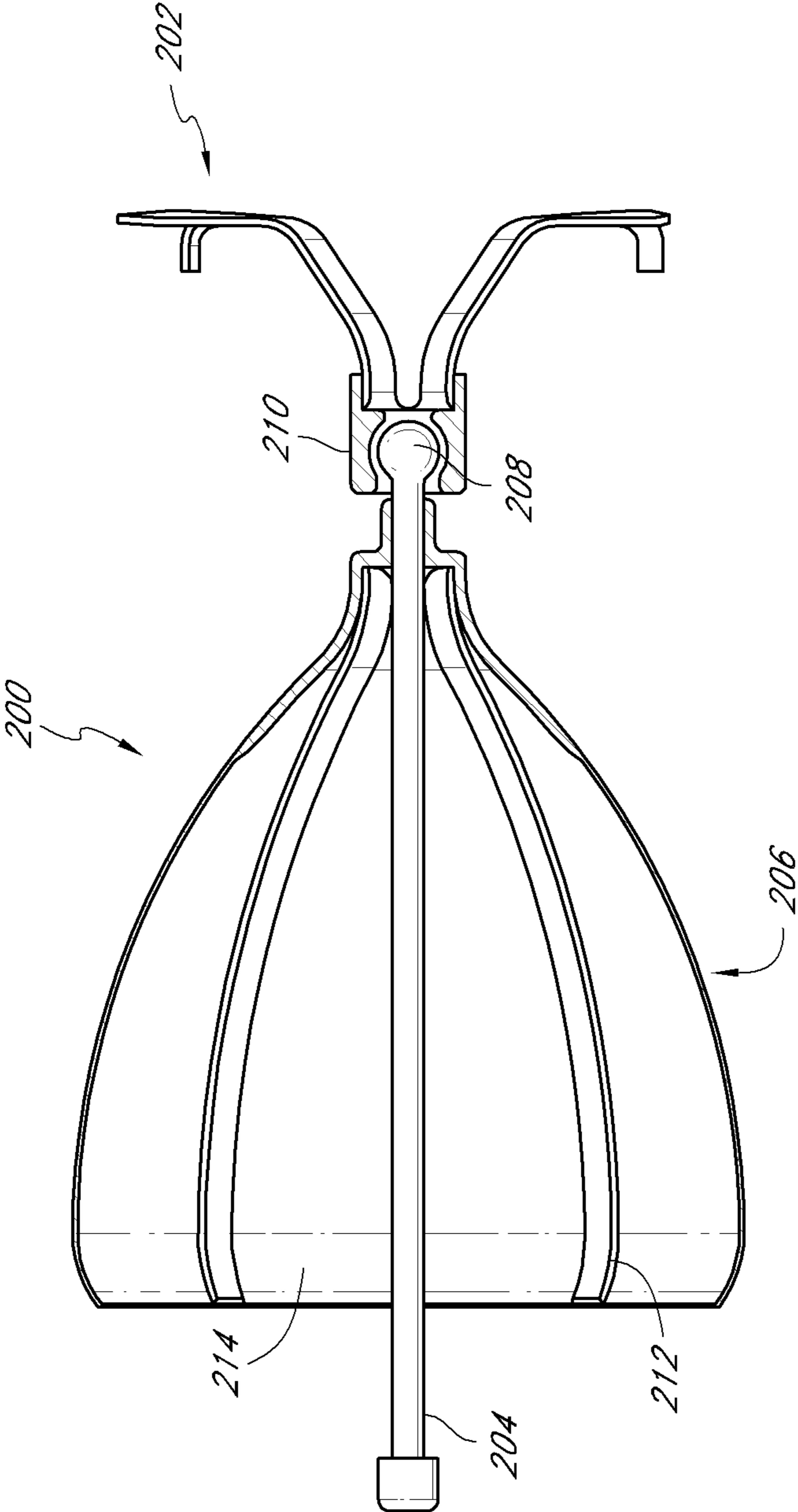


FIG. 5

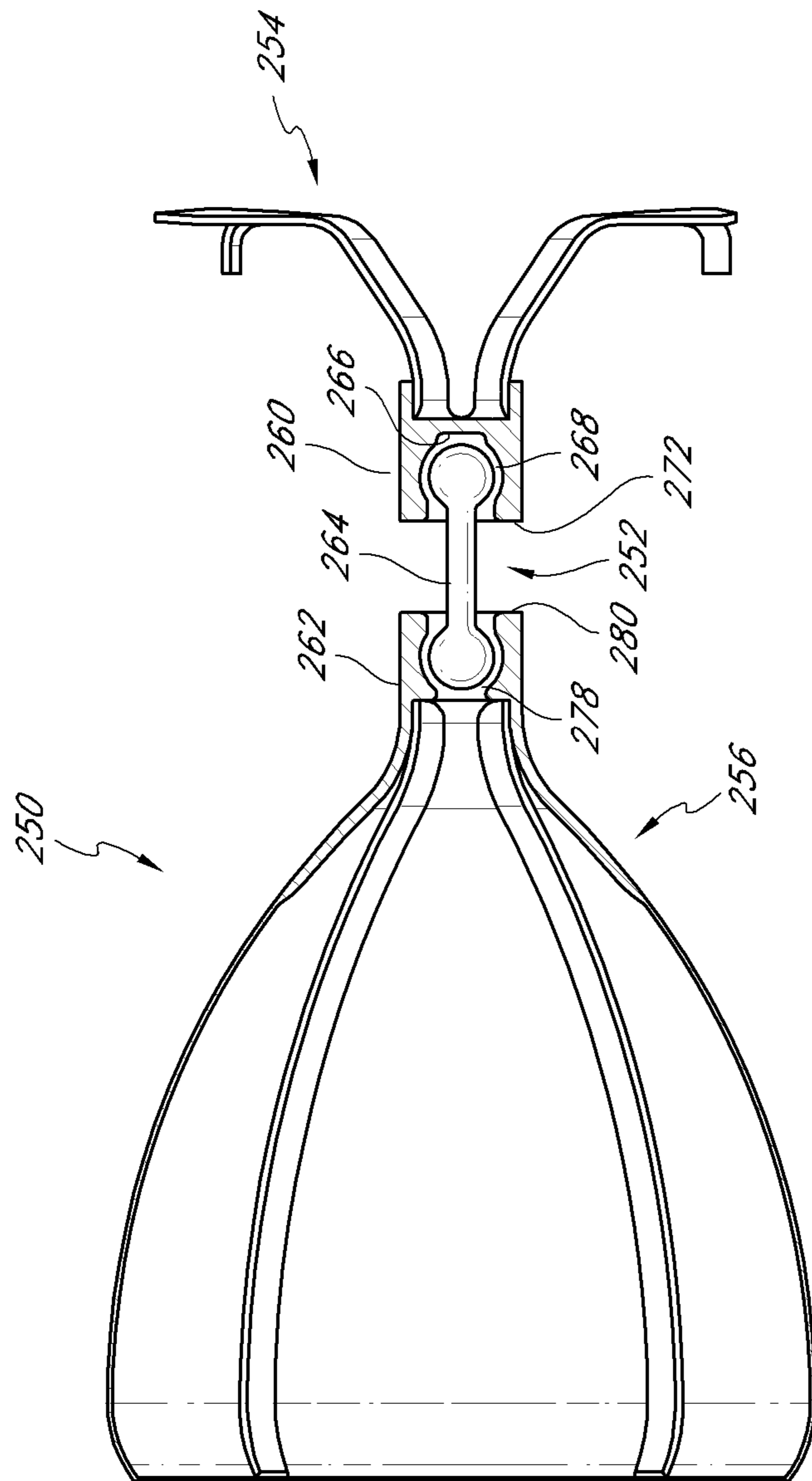


FIG. 6



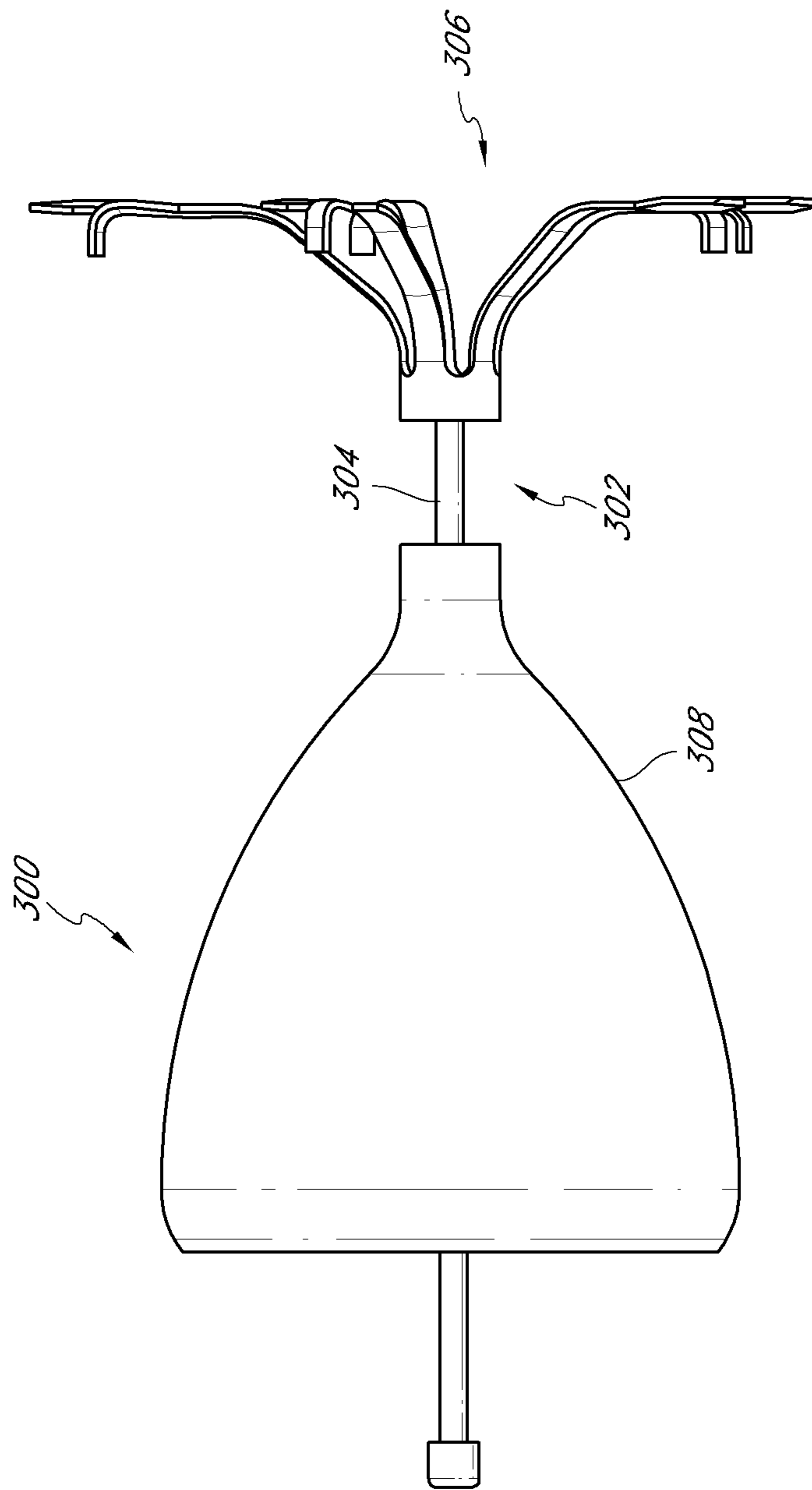


FIG. 7

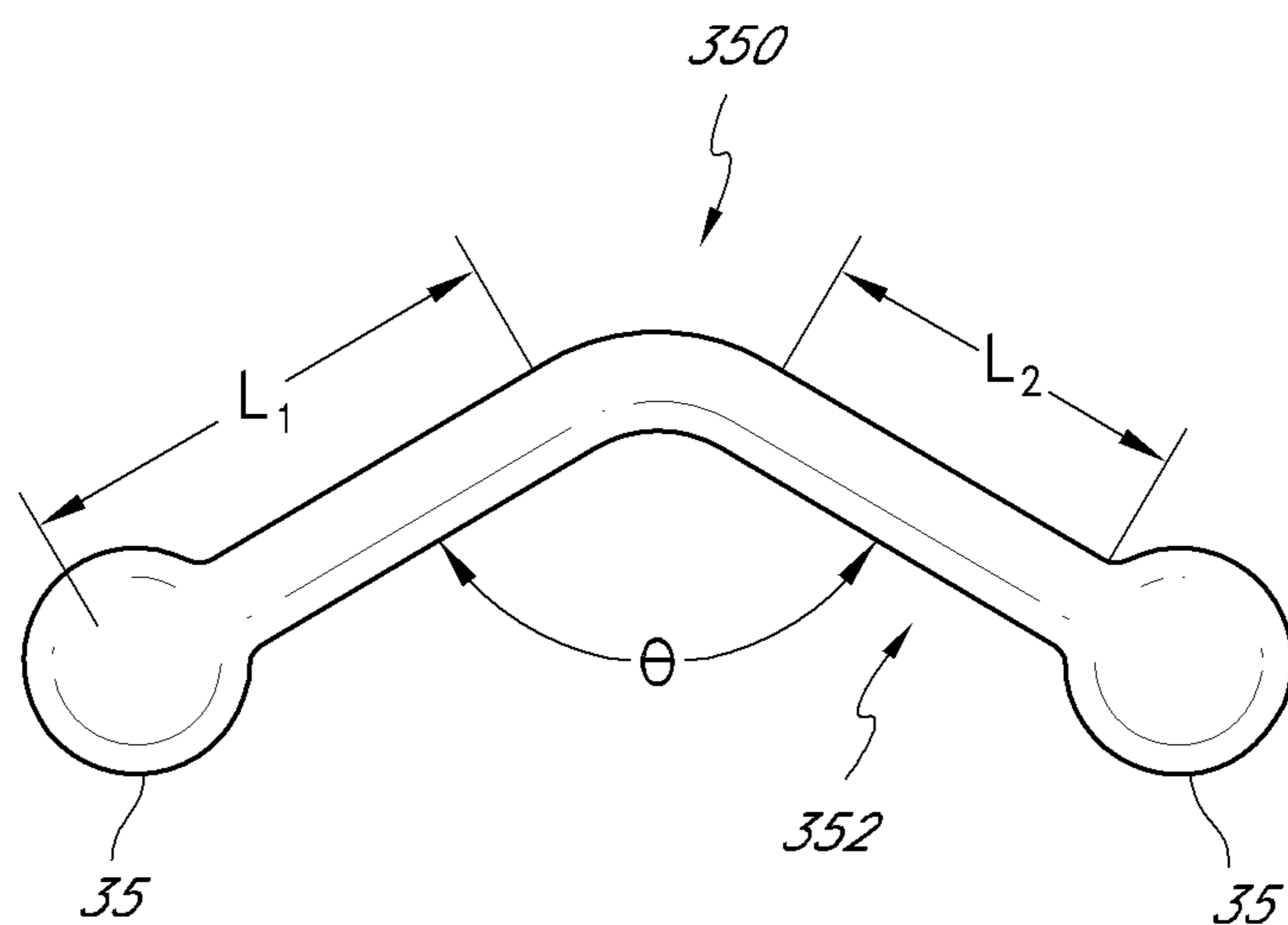


FIG. 8



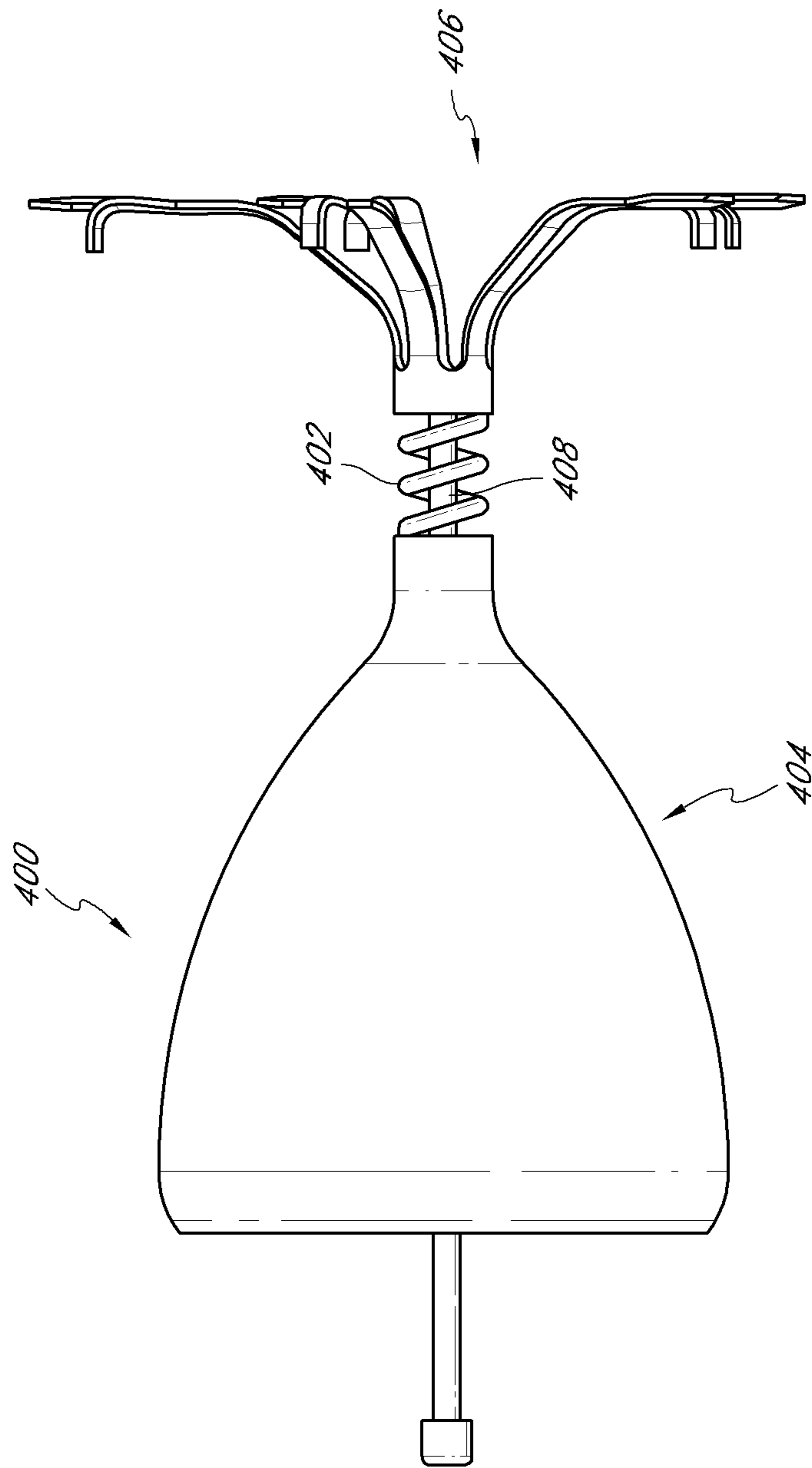


FIG. 9

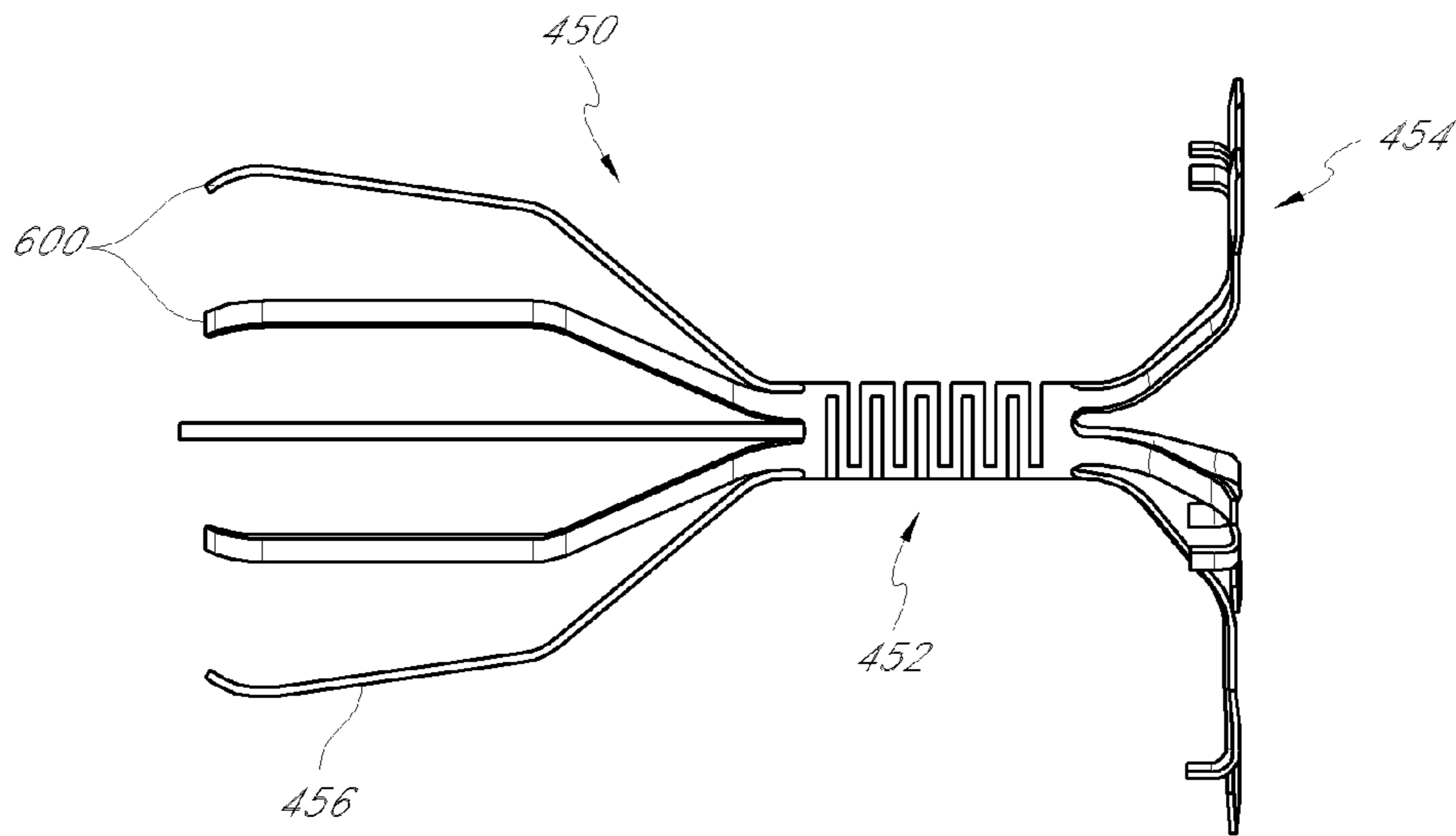


FIG. 10A

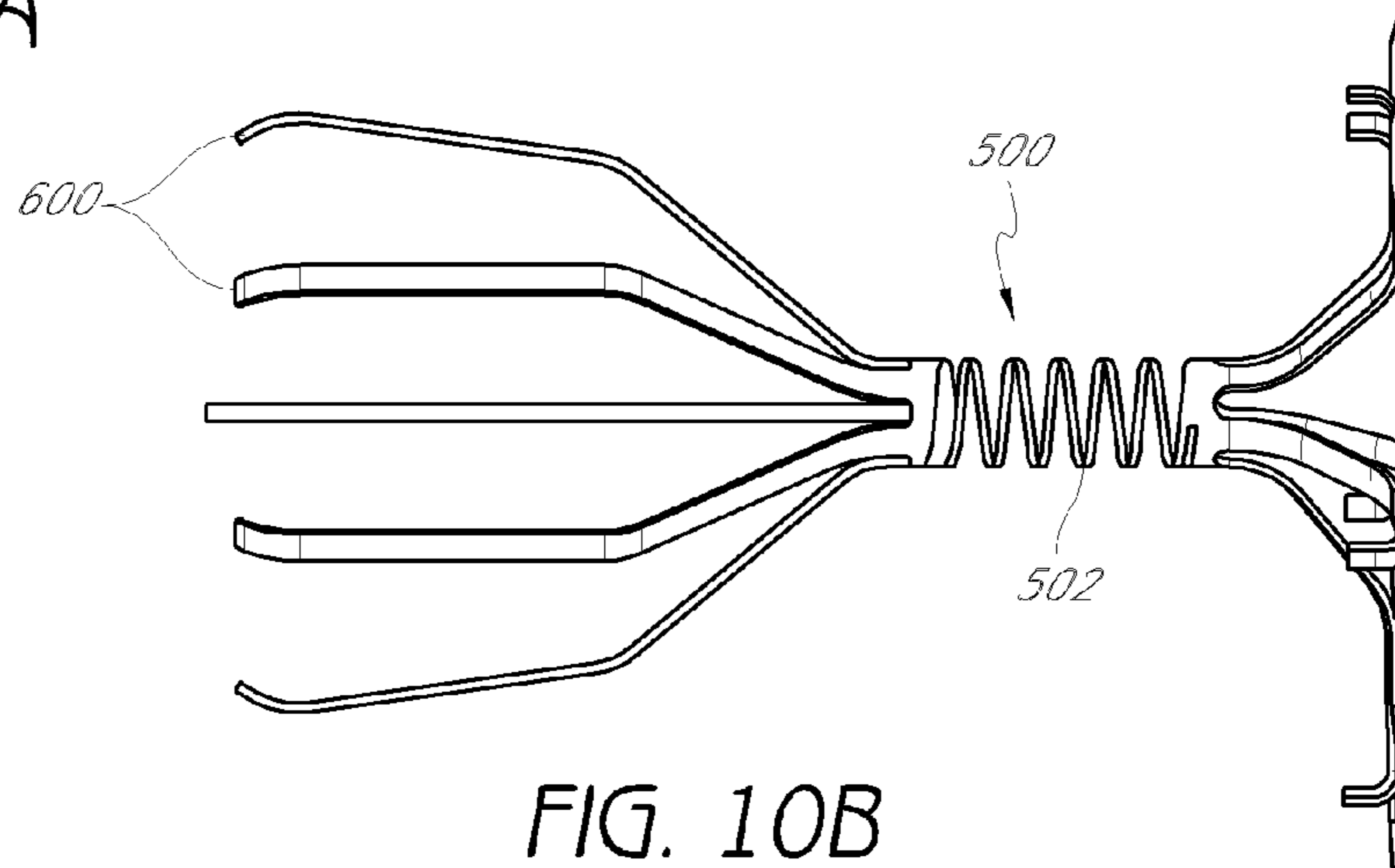


FIG. 10B

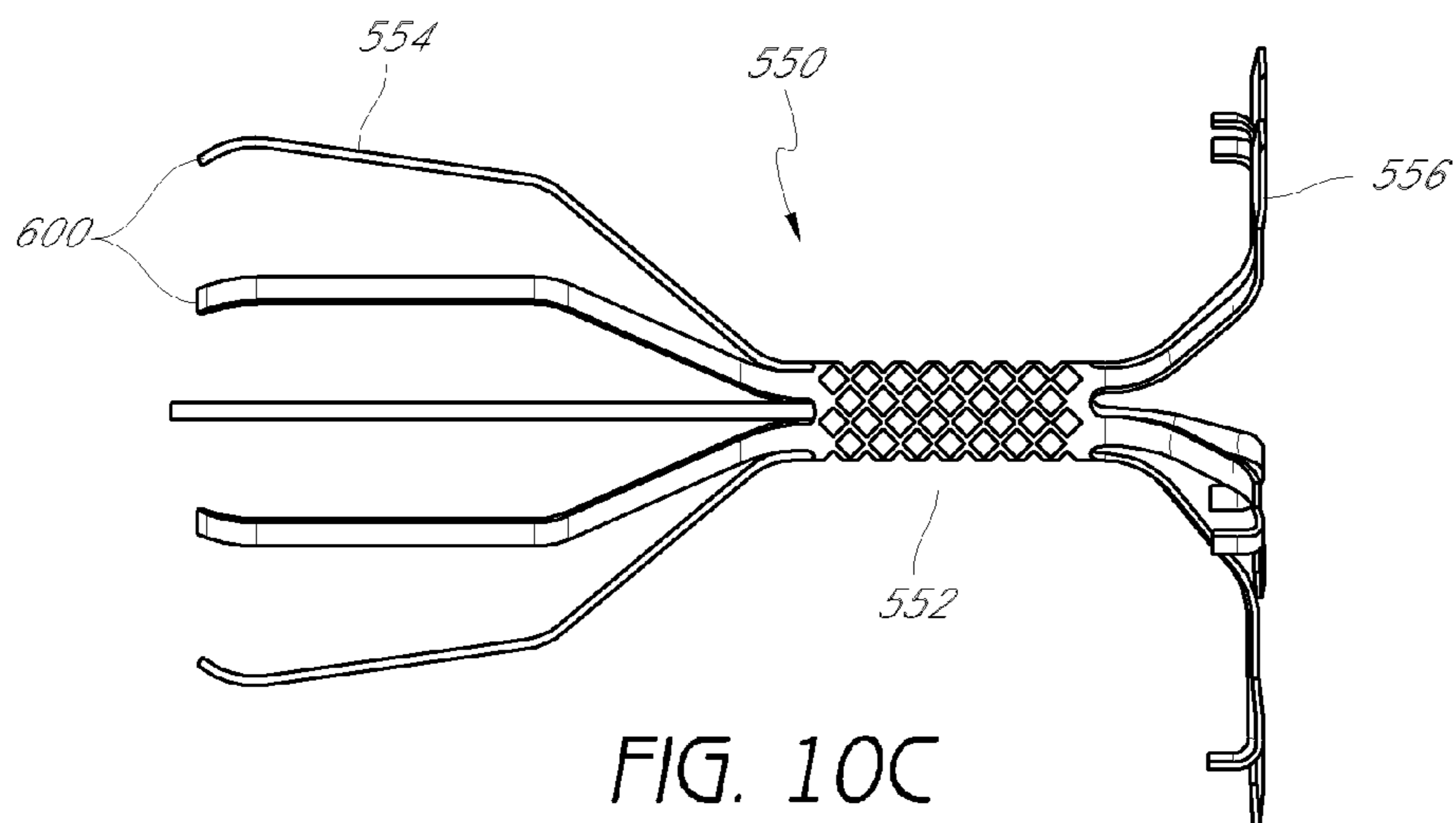


FIG. 10C



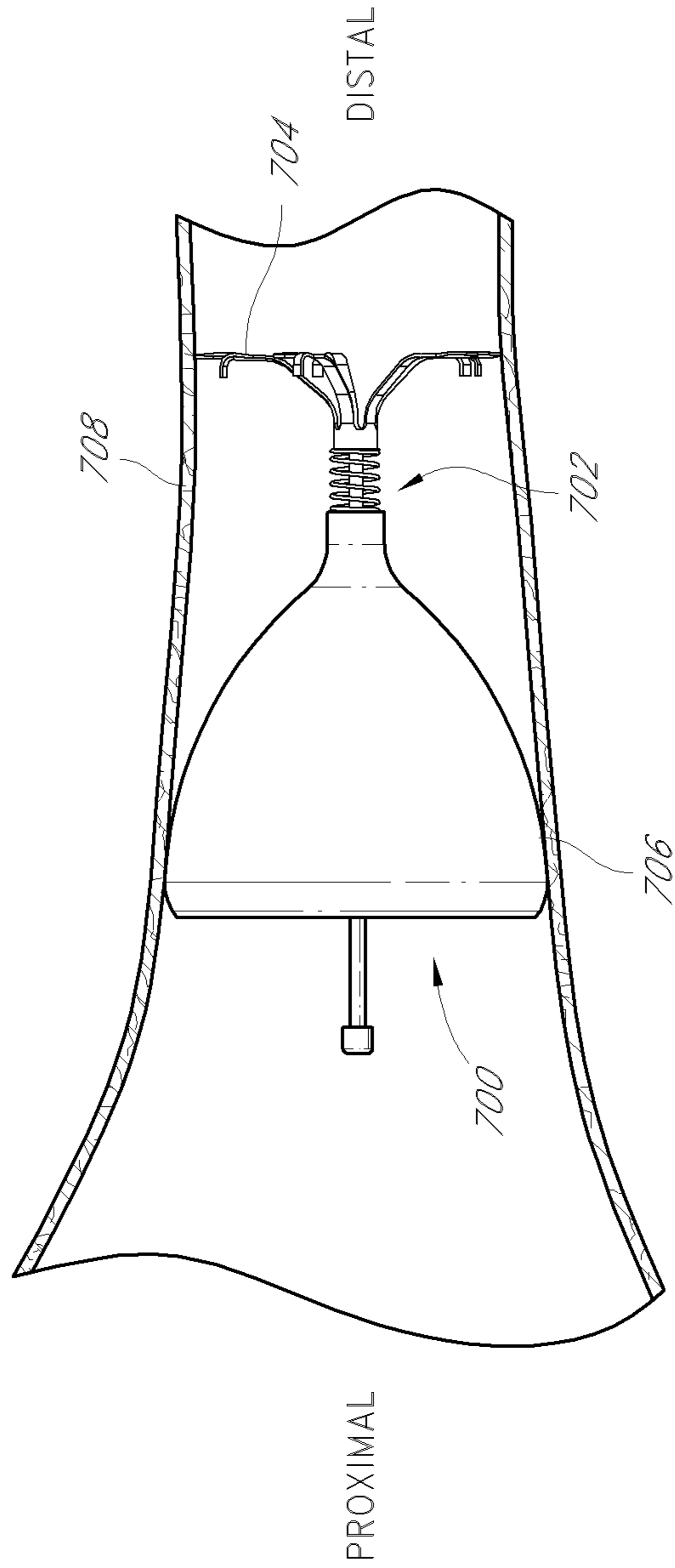


FIG. 11

## ARTICULABLE ANCHOR

## RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/754,394, filed Apr. 5, 2010, which is a continuation of U.S. application Ser. No. 11/585,415, filed Oct. 24, 2006, now issued as U.S. Pat. No. 7,691,151, which claims the benefit under 35 U.S.C. 119(c) to U.S. Provisional Patent Application No. 60/787,995, filed Mar. 31, 2006. The foregoing applications are hereby incorporated by reference in their entirety.

## BACKGROUND OF THE INVENTION

## 1. Field of the Invention

The inventions relate in general to the field of pulmonary treatments, and specifically to systems, devices, and methods for treating a patient's lung or portion thereof.

## 2. Description of the Related Art

Chronic Obstructive Pulmonary Disease ("COPD") has become a major cause of morbidity and mortality in the United States. COPD is typically characterized by the presence of airflow obstructions due to chronic bronchitis or emphysema. The airflow obstructions in COPD are due largely to structural abnormalities in the smaller airways in the lungs.

Mortality, health-related costs, and the segment of the population having adverse effects due to COPD are substantial. COPD is a progressive disease that can severely affect a person's ability to accomplish normal tasks. One method of treating COPD is the insertion of one-way valves into lumens in the lung. The valves inhibit inhalation, but permit exhalation of air already within the lung. The lung presents challenge in mounting such valves because lumens within it are rarely linear over a useful distance. Accordingly, there is a need for a device to permit mounting of valves within non-linear lumens in the lung.

## SUMMARY OF THE INVENTION

Accordingly, one aspect of the invention comprises an implantable device for providing substantially one-way flow of air through a lumen in a human lung to reduce the volume of air trapped in a diseased portion of the lung. The implantable device occludes the lumen to substantially prevent inhalation while substantially permitting expiration out of said diseased portion of the lung. The implantable device is deployable into the lumen with a catheter.

One aspect of an embodiment of the implantable device can comprise a one-way valve being generally umbrella-shaped in configuration. The valve is collapsible for containment within a delivery catheter and expandable in situ when deployed. The valve substantially occludes the lumen. The valve is configured so that when deployed in an orientation to substantially preclude inhalation, inhaled air is prevented from flowing past the valve into said lung by capturing said air within the umbrella-shaped valve. The air exerts an outward force on the umbrella shape and forces said valve to tightly engage the lumen. The valve is configured to permit expiration to occur between the perimeter of the valve and the lumen.

The valve also defines a longitudinal axis and comprises a plurality of metal struts that define a generally bell-shaped frame. Each of the struts have a first end that curves slightly inward towards the longitudinal axis of said implantable device when deployed and a second end proximal a junction

of the second ends of the other struts. The valve also has a resilient membrane that wraps around at least a part of the metal struts and is supported by them. The membrane extends from the junction of the plurality of metal struts toward the first end of said struts. The valve also comprises a central post with a first part that extends within the membrane from the junction of said plurality of metal struts at the center of the bell-shaped frame. The post has a flange at an end distal from the strut junction. The flange is configured to permit deployment, positioning, and recapture of said implantable device. The central post further comprises a second part that extends axially outside the membrane.

Another aspect of the invention comprises an anchor for securing the implantable device within the lumen by inhibiting migration of the device once deployed. The anchor comprises a plurality of resilient arms extending outwardly and radially from the second part of the central post. Each of said arms are configured so as to be collapsible for containment within a delivery catheter and expandable to engage the lumen when deployed in situ. Each of the arms comprises a generally tapered distal end to permit the arm to penetrate the wall of the lumen. The arms further comprise a planar member proximal the tapered distal end and positioned at an angle to the arm to limit advancement of said arm into the lumen wall by contacting the surface of said lumen wall.

Another aspect of the invention comprises a mechanism connecting the one-way valve to the anchor and being disposed generally along the longitudinal axis when the device is in a collapsed state. The mechanism is configured to permit the valve to be oriented at an angle to the anchor when deployed, thereby allowing the anchor to be positioned in a section of the lumen that is at an angle to a section of said lumen in which the one-way valve is positioned. The mechanism comprises at least one connector at a first end to connect the mechanism to the valve. In some embodiments, the mechanism comprises a flexible member configured to be articulable to permit angled orientation of the anchor. In some embodiments, the flexible member comprises a helical spring. In some embodiments, the flexible member comprises a generally cylindrical mesh.

In some embodiments of the connector, a second end of the mechanism comprises a generally spherical connector. In some embodiments, the second end of the mechanism resides in a cavity within the anchor. In some embodiments the cavity is elongated. In some embodiments, the first end of the mechanism comprises a generally spherical connector.

In some embodiments, a cavity is within the anchor, wherein the first end of the mechanism can reside. In some embodiments, the implantable device comprises a second end of the mechanism which comprises a generally spherical connector. In some embodiments, the second end of the mechanism resides in a cavity within the valve. In some embodiments, at least one of the cavities is elongated.

Another aspect of an embodiment is an implantable device for deployment in an anatomical lumen wherein the device comprises an occluding device and an articulable anchor for securing the occluding device within the lumen in a manner that permits the anchor to articulate substantially with respect to said occluding device. The articulable anchor comprises a mechanism connecting said anchor to the occluding device. Additionally, the mechanism comprises at least one connector at a first end to connect said mechanism to at least one anchoring member and the articulable anchor includes a cavity.



## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an implantable device with a one-way valve, an anchor, and a connector;

FIG. 2 is a side view of an implantable device with an articuable anchor.

FIG. 3 is a cross-sectional view of the device of FIG. 2.

FIG. 4 is a cross-sectional view of an air passageway and an implantable device with an articuable anchor that spans a bifurcated air passageway;

FIG. 5 is a cross-sectional view of an implantable device with an articuable anchor in accordance with another embodiment;

FIG. 6 is a cross-sectional view of an implantable device with an articuable anchor in accordance with another embodiment;

FIG. 7 is a side view of an implantable device with an articuable anchor in accordance with another embodiment;

FIG. 8 is a side view of a flexible connector for use in an implantable device with an articuable anchor;

FIG. 9 is a side view of an implantable device with an articuable anchor having a biasing member and a connector positioned between an obstruction member and the anchor system;

FIGS. 10A-10C are side views of alternative embodiments of frames for implantable devices with articuable members embodied as flexible connectors; and

FIG. 11 is a cross-sectional view of an air passageway and a flexible implantable device positioned in the air passageway

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 illustrates an implantable device in an expanded position. The implantable device 10 is configured to affect airflow in an air passageway in a lung. The implantable device comprises an anchor 12 and an obstruction member 14. A connecting mechanism 16 couples the anchor 12 to the obstruction member 14. The illustrated implantable device 10 includes a support structure 18 that can form the frame of the implantable device 10. At least a portion of the anchor 12, the connecting mechanism 16, and the obstruction member 14 can be formed by the support structure 18. An elongated member 20 extends axially through obstruction member 14 and can be directly or indirectly coupled to the support structure 18.

The obstruction member 14 surrounds at least a portion of the elongated member 20 and is configured to interact with an anatomical lumen, such as an air passageway, to regulate the flow of fluid through the lumen. The obstruction member 14 can effectively function as a one-way valve. One example of an obstruction member is an occluding device.

The anchor 12 comprises a plurality of anchor members 22 that extend from the connecting mechanism 16. In the illustrated embodiment, each of the anchor members 22 is an elongated member that extends radially outward from the connecting mechanism 16 and terminates at a piercing end 24, although the anchor members 22 can have any number of piercing ends. One or more stops 26 can be positioned along each anchor member 22, preferably positioned at some point near the piercing members 24. The stops 26 can be configured to limit the puncturing by the piercing member 24 through lung tissue beyond a desired depth.

The stops 26 can be formed by splitting the distal ends of the anchor members 22. One of the split sections can be bent downwardly to form the stop 26, while leaving the second split section to extend outwardly to form the piercing member

24. Although the stops 26 can be formed integrally with the anchor member 22, the stops 26 can also be applied in a subsequent process. For example, each stop 26 can be a piece of metal that is mounted to the anchor members 22. Thus, each of the anchor members 22 can be of a one piece or multi-piece construction.

Any number of anchor members 22 can be used to limit migration of the implantable device 10 implanted at a desired deployment site. The illustrated implantable device 10 comprises five anchor members 22 that are coupled to the connecting mechanism 16. However, the anchor 12 can comprise any suitable number of anchor members in any various configurations. A skilled artisan can select the number of anchor members 22 based on the size of an air passageway, anchor design, and the like. The anchor members 22 can be positioned at regular or irregular intervals. When the anchor 12 is positioned in situ, the piercing members 24 can engage tissue of an air passageway wall of a lung to retain the implantable device 10 at a desired location. One non-limiting example of such an engagement occurs when at least one piercing member punctures the wall of the air passageway.

With continued reference to FIG. 1, the obstruction member 14 is generally umbrella-shaped and comprises an obstructing member frame 28 that carries a membrane 32. The obstructing frame 28 includes a plurality of arcuate struts 30 that support the membrane 32.

A plurality of pathways can be defined by the obstruction member 14 between each pair of struts 30. When the implantable device 10 is securely anchored in a lung passageway, the struts 30 can bias the obstruction member 14 outwardly against the air passageway wall. Between each pair of struts 30, the membrane 32 can define the pathway that permits mucus transport past the obstruction member 14 through the associated air passageway.

Proper mucociliary functioning can be maintained to ensure that the respiratory system continues to self clean after an implantable device has been deployed. To maintain mucociliary transport the membrane 32 can be folded inwardly away from the air passageway wall, especially during exhalation when the implantable device 10 has the anchor 12 positioned distally. The membrane 32 can press lightly against the air passageway wall in order to permit ciliary action for the movement of mucus past the membrane 32. Of course, the implantable device can have other configurations that permit mucus transport.

The membrane 32 can be treated to enhance sealing, improve biostability, and/or enhance mucus transport. To enhance valving action, the membrane 32 can be treated with a material that interacts with a wall of an air passageway to improve functioning. A coating on the membrane can reduce airflow in at least one direction between the air passageway and the expanded membrane engaging the air passageway wall. The coating can be a hydrogel that helps the membrane 32 adhere to the air passageway wall to further limit air flow past the implantable device in at least one direction. Other coating materials can be applied to the membrane or other portions of the implantable device depending on the intended application. The coating can be applied before, during, or after the implantable device is placed in a passageway.

In some embodiments, the membrane 32 can be coated with a lubricious material to limit adherence to an air passageway. Additionally, an implantable device may partially or fully collapse when subjected to rapid pressure changes, such as when a person coughs. If the membrane is folded together, the lubricious material can inhibit sticking of the membrane to itself so that the implantable device can quickly re-expand to function effectively again.



## 5

The implantable device can be adapted to facilitated movement through a delivery lumen. To reduce frictional forces between the implantable device and a lumen of a delivery instrument, a release agent can be applied to the implantable device. The release agent can reduce the force required to eject the implantable device out of the lumen as detailed above.

The struts can have first strut ends connected to the connecting mechanism 16 and opposing second strut ends. The proximal tips of the struts can curve radially inward toward the longitudinal axis of the implantable device 10.

With continued reference to FIG. 1, the elongated member 20 comprises a rod 34 that is connected to the connecting mechanism 16 and a gripping head 36. The rod 34 is a generally cylindrical body that extends along the longitudinal axis of the implantable device 10, although the rod 34 can be at other suitable locations. For example, the rod 34 can be angled or offset from the longitudinal axial of the implantable device 10.

The rod 34 is connected to the gripping head 36 that is positioned exterior to the chamber defined by the membrane 32. The rod 34 extends from the opening such that the gripping head 36 is spaced outwardly from the opening defined by the membrane 32. The elongated member 20 can be of such a length that it extends beyond the second end of the struts when the implantable 10 occupies an expanded position. When the gripping head 36 is spaced from the proximal ends of the struts and the membrane 32, a removal device (not shown) can easily grip the exposed gripping head 36. In alternative embodiments, the rod 34 terminates to form the gripping head 36 positioned inwardly of the opening defined by the member 32. Other embodiments of the gripping head 36 can include various changes in shape and size of the gripping head 36 to cooperate with different coupling mechanisms.

The elongated member 20 can also be of such a length that the elongated member 20 and the struts 30 extend substantially the same distance from the connecting mechanism 16 when the implantable device 10 is in a fully collapsed state (not shown). The struts 30 can lie flat along the rod 34 for a low profile configuration. The gripping head 36 preferably remains exposed so that the implantable device 10 can be pushed out of a delivery instrument by conveniently applying a force to the gripping head 36.

A variety of removal devices can be used to engage the implantable device to, for example, reposition, re-implant, or remove the implantable device as discussed above. The enlarged gripping head 36 can be designed to facilitate removal of the implantable device 10 by any of numerous extracting devices and methods as are known in the art. The removal gripping head 36 can be gripped by a removal device (such as forceps, an extractor, a retractor, gripping device, or other suitable device for gripping a portion of the implantable device 10). A sufficient proximal force can be applied to displace the implanted implantable device 10 from the implantation site. The illustrated gripping head 36 is a somewhat cylindrical knob having an outer diameter that is greater than the outer diameter of the rod 34. The gripping head 36 can have other configurations for engaging a removal device. Exemplary gripping heads can comprise a hook, ring, enlarged portion, connectors (e.g., snap connector, threaded connector, etc), or other structure for permanently or temporarily coupling to a removal device.

FIG. 2 is a side view of an embodiment of an implantable device 50. The obstruction member 58 is coupled with the anchor 56 by a connecting mechanism 52. In the illustrated embodiment, the connecting mechanism 52 comprises a connecting member 54. The connecting mechanism 52 permits

## 6

articulation between the obstruction member 58 and the anchor 56. In the illustrated position, the obstruction member 58 and the anchor 56 are collinear along the longitudinal axis of the implantable device 50. Through articulation of the connecting mechanism 52, the obstruction member 58 and the anchor 56 can be configured to no longer be collinear along the longitudinal axis of the implantable device 50. As one non-limiting example, the obstruction member 58 can be maintained at an unaltered orientation while the connecting mechanism 52, either by pivoting or flexing, can continue to couple the obstruction member 58 to the anchor 56 while the anchor 56 is moved to a different orientation than that of the obstruction member 58. In some embodiments, the connecting mechanism 52 can permit axial movement, changing the distance between the distal end of the obstruction member 58 and the proximal end of the anchor 56. In some embodiments, the articulation of the connecting mechanism 52 is accomplished through discrete pivotal orientation changes. In other embodiments, the connecting mechanism 52 is configured to articulate through continuous flexing, such as the bending of a flexible member. In still other embodiments, the connecting mechanism 52 can be configured to permit changes in orientation between the obstruction member 58 and the anchor 56 by limiting separation between the obstruction member 58 and the anchor 56 when the connecting mechanism 52 is not rigidly coupled to the two components. In these embodiments, the connecting mechanism 52 can comprise a tether or other limiting component.

FIG. 3 is a cross-sectional view of another embodiment of an implantable device 100. The implantable device 100 is configured to permit an angled position. The implantable device 100 can be positioned in a naturally angled air passageway (e.g., a bifurcated air passageway, tortuous air passageway, etc.) in a lung. The implantable device 100 has an anchor sufficiently articulable so as to permit deployment of the implantable device 100 within the angled air passageway without substantially altering the natural geometry of the air passageway. The implantable device 100 can effectively function even though the obstructing member 102 conforms to the natural shape of the air passageway. The implantable device 100 can be generally similar to the implantable device 10 of FIG. 1, and accordingly, the following description of the implantable device 100 can equally apply to the implantable devices described below, unless indicated otherwise.

As used herein, the term "implantable device" is a broad term and is used in its ordinary meaning and includes, without limitation, articulated implantable devices, actuatable implantable devices, and other implantable devices that have one or more means for providing articulation, actuating, or flexibility between an anchor and a functional member, such as an obstruction member. The implantable devices may have any number of pivot points or flexible portions. These implantable devices can be placed along tortuous pathways, such as a section of a lung passageway that is substantially curved along its length. Some embodiments include a means for providing flexibility that comprises any combination of a biasing member, a flexible member, a ball and socket arrangement, a joint, a linkage, a hinge, and/or a flexible connector. As such, the flexible implantable device can be selectively curved or angled along its length to match the shape of the air passageway.

The illustrated implantable device 100 comprises an obstructing member 102 articulably and pivotally connected to an anchor system 104. The anchor system 104 can be moved relative to the obstructing member 102 to a desired position depending on the functional application of the device 100. An articulating connecting portion 106 connects and



permits movement between the obstructing member **102** and the anchor system **104**. The articulating connecting portion **106** permits articulation of the device **100** such that the device **100** can be implanted in curved air passageways without significantly altering the natural geometry of the air passageway. For example, the implantable device **100** can span a bronchial branching section of a lung. The implantable device **100** can be articulated repeatedly (e.g., during normal lung functioning) without appreciable trauma to the lung, or to the implantable device **100**. Traditional stent-based devices for implantation in air passageways are typically rigid elongated structures that are not suitable for placement in bifurcated or substantially curved air passageways. These stent-based devices maintain their linear configuration thus rendering them unsuitable for use in these types of air passageways.

With reference again to FIG. 3, the articulating connecting portion **106** can have various configurations for permitting relative movement between the anchor system **104** and the obstructing member **102**. In some embodiments, including the illustrated embodiment, the articulating connecting portion **106** comprises at least one ball and socket arrangement. The illustrated anchor system **104** has an anchor socket **120** comprising a generally spherical cavity that holds one end of the connecting rod **124**, while the obstructing member **102** has an obstructing socket **122** that holds the other end of the connecting rod **124**.

The connecting rod **124** has a first end **128** and an opposing second end **126**. Each of the ends **126**, **128** is generally spheroidal and sized to be received by the corresponding socket **122**, **120**. The spheroidal shape the ends **126**, **128** can be integral with the connecting rod **124** or generally spheroidal-shaped members can be coupled to or mounted on the ends **126**, **128**. The first end **128** is rotatably mounted in the obstructing socket **122**. The second end **126** is rotatably mounted in the anchor socket **120**. As such, the sockets **120**, **122** can rotate freely about the ends of the connecting rod **124**. Thus, the implantable device **100** has a plurality of joints that permit articulation. The implantable device can have any number of articulable connecting portions for a particular application.

To reduce wear of the balls and the sockets, the surface(s) of the sockets and/or ends **126**, **128** can be coated with a material to reduce frictional interaction. For example, the interior surface **130** of the anchor socket **120** can comprise one or more of the following: a somewhat lubricious material (e.g., Teflon®), ceramics, metals, polymers (preferably hard polymers), or combinations thereof. However, other materials can be utilized to limit or inhibit wear between the connecting rod **124** and the obstructing member **102** and/or the anchor system **104**. When the implantable device **100** is deployed in the lungs, the anchor socket **120** can move, preferably slightly, with respect to the ball at the second end **126** during normal respiration. The wear-resistant surfaces can minimize debris build up that can impede performance of the implantable device **100**. In view of the present disclosure, one of ordinary skill in the art can determine the appropriate combination of materials, geometry of the ball and socket arrangement, and the length of the connecting rod **124** to achieve the desired positioning of the implantable device **100**.

The connecting rod **124** can have a one-piece or multi-piece construction. In some embodiments, the connecting rod body **142** and the ends **126**, **128** are formed of a single material (e.g., a metal such as Nitinol or titanium). In other embodiments, the connecting rod body **142** is formed of a flexible material, and the ends **126**, **128** are formed of a somewhat hard, rigid material, such as a ceramic.

The connecting rod **124** can be generally straight, as shown in FIG. 3. However, the connecting rod **124** can have other configurations based on clinical need. For example, the connecting rod **124** of FIG. 8 has an angled shape that allows placement of the implantable device in a complex shaped airway (e.g., an airway with sharp curves, branching portions, etc.).

With continued reference to FIG. 3, an elongated member **134** includes a rod **138** having an end portion **140** that is connected to the obstructing member frame **136**. The end portion **140** can be connected to the frame **136** by one or more mechanical fasteners, adhesives, welding, bonding, interference fit, threads, or other suitable coupling means for securely coupling the rod **138** to the frame **136**. In some embodiments, including the illustrated embodiment, the rod **138** is connected to the interior portions of the struts **110**, although the rod can be connected to other portions of the frame **136**. The rod **138** can also be formed integrally with at least a part of the frame.

As shown in FIG. 4, the implantable device **150** can be placed at a branching air passageway of the bronchial tree. The obstructing member **152** is within a proximal passageway **160** and the anchor system **154** is positioned within a distal sub-branch air passageway **162**. The implantable device **150** can therefore span the junction **164** of the air passageway of the lung and, thus, permits flexibility in positioning of the device **150**. The air passageway can generally retain its natural shape, such as its shape before implantation of the implantable device **150**, to minimize trauma to the lung tissue. The orientations of the implantable devices are not limited solely to the illustrated orientations. The implantable device **150** can be reversed from the illustrated orientation so that the anchors are located proximally of the obstructing member. Thus, the implantable device **150** can be oriented to permit air flow in any desired direction.

The implantable device **150** can also be implanted in non-branching portions of lungs. If desired, the implantable device **150** can be implanted in continuous air passageways that are generally straight, curved, angled, or having any other configuration. Because the implantable device **150** can assume various configurations, there is significant flexibility in selecting a deployment site. The implantable device **150** can also be implanted in air passageways that have a substantially constant or varying cross-section. Advantageously, the physician can implant the implantable device **150** at various locations throughout the lung to treat specific portions of the lung. If the implantable devices are in the form of occluding devices or flow regulating devices (e.g., a one-way valve, flow resistor, etc.), these devices can be implanted proximally of, and adjacent to, the diseased portions of a lung, thus maximizing the amount of healthy lung tissue that can function, even if the diseased lung tissue is in the far distal portions of the bronchial tree.

FIG. 5 illustrates an implantable device **200** that comprises an anchor system **202** that is pivotally coupled to an elongated member **204** that extends through the obstructing member **206**. The elongated member **204** has a generally spheroidal member **208** that is rotatably mounted in an anchor socket **210** of the anchor system **202**. The obstructing member **206** can be fixedly attached at some point along the elongated member **204**.

To secure the obstructing member **206** to the elongated member **204**, a portion of an obstructing member frame **212** and/or a membrane **214** can be coupled to the elongated member **204**. In the illustrated embodiment, the struts of the



obstructing member frame **212** and the membrane **214** are both coupled to the outer surface of the elongated member **204**.

Once deployed, the implantable device **200** illustrated in FIG. **5** can be retained in place by the anchor system **202**. The implantable device **200** can be positioned in a non-linear lumen, such as those illustrated in FIG. **4**, because the anchor system **202** may remain at a first orientation while the obstructing member **206** is pivoted to a second orientation by the generally spheroidal member **208** and the anchor socket **210**. The obstructing member **206** can be configured to move axially from the anchor system **202** through travel along the elongated member **204**, which can be limited to prevent inefficient operation of the implantable device **200**.

FIG. **6** is a cross-sectional view of a implantable device **250** that has an articulable connecting portion **252** that permits axial movement between an anchor system **254** and an obstructing member **256**. The connecting portion **252** includes a holder **260** of the anchor system **254** and a holder **262** of the obstruction member **256**. Each of the holders **260**, **262** is configured to receive an end of a connector **264**. The illustrated connector **264** has enlarged ends that are held by the holders **260**, **262**. The chambers **268**, **278** of the holders **260**, **262**, respectively, permit axial movement of the connector **264**. The enlarged ends of the connector **264** that are held by the holders **260**, **262** can also be constructed to permit pivotal movement in addition to axial movement.

The anchor system **254** and the obstructing member **256** of the device **250** can move freely towards and away from each other. However, one or more biasing members (not shown) can be positioned between the anchor system and obstructing member of the implantable device to adjust positioning of the implantable device. The biasing member can cooperate with the connecting portion to ensure that the implantable device remains in a desired position.

FIG. **7** illustrates an implantable device **300** that has an articulating connecting portion **302** that includes a flexible member **304** connected to the anchor system **306** and the obstructing member **308**. The flexible member **304** can comprise a somewhat flexible elongated member (e.g., a solid rod, a hollow tube, ribbon, etc.) and can comprise metal, polymers (preferably a somewhat rigid polymer), filaments, and the like. The flexible member **304** preferably does not substantially stretch or buckle when an axial force is applied thereto. Alternatively, the flexible member **304** can be configured to allow significant axial movement between the anchor system **306** and the obstructing member **308**. The flexible member **304** can be, for example, a tether that holds together and limits the axial movement of the anchor system **306** away from the obstructing member **308**. However, the flexible member **304** may be easily collapsed as the anchor system **306** is moved towards the obstructing member **308**. The flexible member **304** can comprise a rope, wire, filaments, or other suitable member for providing relative movement between the anchor system **306** and the obstructing member **308**.

With reference to FIG. **8**, the connecting rod **350** can have or bend to have an angled central portion **352** that defines an angle  $\theta$ . The length **L1** and **L2** can be selected to achieve the desired orientation and size of an implantable device. If the implantable device is deployed at a sharp bend of an air passageway, the angle  $\theta$  can be matched with the angle of the bend to generally align the longitudinal axis of an anchor system with one of the passages and the longitudinal axis of an obstructing member with the other passage. The implantable device, for example, can include a connecting rod for deployment in air passageways that together form an acute

angle. Accordingly, the configuration of the connecting rod **350** can be selected based on the target deployment site.

As illustrated in FIG. **9**, the implantable device **400** can have a biasing member **402** positioned between an obstructing member **404** and an anchor system **406**. One example of such a biasing member is a helical spring. In the illustrated embodiment, a tether **408** extends through the biasing member **402** between the obstructing member **404** and the anchor system **406**. Other embodiments can have a tether **408** connecting the obstructing member **404** and an anchor system **406** that does not extend through the biasing member **402** and instead passes at least partially outside the biasing member **402**. Alternatively, a flexible cylindrical member (not shown) can extend between the obstructing member **404** and the anchor system **406**, substantially completely enclosing the biasing member **402**. The tether can also be a connector such as the one illustrated in FIG. **7**.

FIGS. **10A-10C** illustrate various embodiments of support frames of implantable devices, each having a means for flexing. Each of the support frames has a flexible connecting portion that permits relative movement between an anchor system and an obstructing member frame. The frames as illustrated do not have membranes; however, any of various types of membranes can be applied to the obstructing member frames. FIG. **10A** illustrates a frame support **450A** that includes a flexible connecting portion **452A** in the form of slots in an alternating pattern. The connecting portion **452A** can be an integral piece with the frame, as illustrated, or can be coupled or mounted to an anchor system **454A** and an obstruction frame **456A**. The flexible connecting portion **452A** can be formed by cutting slots out of a tube. The number and size of the slots can be selected to achieve the desired flexibility. Additionally, the material used to construct the connecting portion can be selected for its flexibility characteristics.

FIG. **10B** illustrates a frame support **500B** that is generally similar to the frame support **450A** of FIG. **10A**. In the illustrated embodiment, the frame support **500B** includes a flexible connecting portion **502B** in the form of a spring member extending axially along the longitudinal axis of the frame support **500B**. As such, the spring member can be arranged in a spiral fashion about the longitudinal axis of the flexible connecting portion **502B**. The illustrated spring member is in the form of a helical spring, although other types of springs or resilient members can be utilized. The spring can comprise the connecting member alone or can act as a biasing member, as described above. Additionally, as described above, the spring can be formed integrally with the frame, or serve as a coupler for both an anchor system and obstruction frame.

FIG. **10C** illustrates a frame support **550C** that comprises a flexible connecting portion **552C** comprising a mesh. The connecting portion **552C** can comprise a mesh of various sizes, with large or small mesh spaces. Additionally, the mesh can be constructed of a variety of materials, such as metals, synthetics, or any other resilient material. The mesh can permit flexing, as when the obstructing frame **554C** and anchor system **556C** are positioned at different orientations, as described above. In some embodiments, the mesh can also permit axial compression along the longitudinal axis of the frame support **550C**. As described, the mesh can be formed integrally with the frame, or be mounted or coupled at either end to the obstructing frame **554C** and anchor system **556C**.

The illustrated struts **600A**, **600B**, **600C** of FIGS. **10A-10C** each have two generally elongated straight portions connected by a bend. The struts **600A**, **600B**, **600C** can also have a continuously curved configuration similar to the struts described above. The frame supports can carry a membrane to



form an obstructing member, such as an obstructing member adapted to function as a valve (preferably a one-way valve). The connecting portions can enhance the seating of the obstructing member within an air passageway to enhance valve functioning.

With reference to FIG. 11, an implantable device 700 is illustrated as having a flexible connecting portion 702, such as the one shown in FIG. 10A. The implantable device 700 is deployed and implanted in an air passageway 708 and is held in place by its anchor system 704. The flexible connecting portion 702 can apply a force to the obstructing member 706 of the implantable device 700 to enhance seating between the membrane of the obstructing member 706 and the wall 708. Thus, a bias of the flexible connecting portion 702 can ensure that an effective seal is maintained between the obstructing member 706 and the wall 708, thereby limiting or preventing the flow of air distally past the implantable device 700. Advantageously, the implantable device 700 can permit the passage of air proximally past the obstructing member 706 when the pressure differential across the implantable device 700 is sufficiently high. As the air flows proximally past the obstructing member 706, the flexible connecting portion 702 can apply a distally directed force. When the pressure differential is reduced a sufficient amount, the obstructing member 706 is pulled distally against the air passageway wall 708 to once again form a seal with the air passageway wall. Thus, the obstructing member 706 can move slightly during normal lung functioning while the anchor system 704 can remain securely fixed in place. The flexible connecting portion 702 can therefore enhance the valving action of the implantable device 700.

If desired, the connecting portion 702 can also be used to position the anchors 704 and the obstructing member 706 along a tortuous path within a lung, as shown in FIG. 4 above. The connecting portion 702 can be positioned along sharp turns that may be unsuitable for rigid valves, such as stent-based devices.

All patents and publications mentioned herein are hereby incorporated by reference in their entireties. Except as further described herein, the embodiments, features, systems, devices, materials, methods and techniques described herein may, in some embodiments, be similar to any one or more of the embodiments, features, systems, devices, materials, methods and techniques described in U.S. patent application Ser. No. 10/409,785 (U.S. Publication 2004-0200484), filed Apr. 8, 2003; Ser. No. 09/951,105 (U.S. Publication No. 2003/0050648A1), filed Mar. 13, 2003; Ser. No. 10/848,571, filed May 17, 2004; Ser. No. 10/847,554, filed May 17, 2004; Ser. No. 10/418,929, filed Apr. 17, 2003; Ser. No. 10/081,712 (U.S. Publication 2002-0112729), filed Feb. 21, 2002; Ser. No. 10/178,073 (U.S. Publication 2003-0154988), filed Jun. 21, 2002; Ser. No. 10/317,667 (U.S. Publication 2003-0158515), filed Dec. 11, 2002; Ser. No. 10/103,487 (U.S. Publication 2003-0181922), filed Mar. 20, 2002; Ser. No. 10/124,790 (U.S. Publication 2003-0195385), filed Apr. 16, 2002; Ser. No. 10/143,353 (U.S. Publication 2003-0212412), filed Mar. 9, 2002; Ser. No. 10/150,547 (U.S. Publication 2003/0216769), filed May 17, 2002; Ser. No. 10/196,513 (U.S. Publication 2004-0010204), filed Jul. 15, 2002; Ser. No. 10/254,392 (U.S. Publication 2004/0059263), filed Sep. 24, 2002; Ser. No. 10/387,963 (U.S. Publication 2004-0210248), filed Mar. 12, 2003; Ser. No. 10/745,401, filed Dec. 22, 2003; U.S. Pat. Nos. 6,293,951; 6,258,100; 6,722,360; 6,592,594, which are hereby incorporated herein and made part of this specification. In addition, the embodiments, features, systems, devices, materials, methods and techniques described herein may, in certain embodiments, be

applied to or used in connection with any one or more of the embodiments, features, systems, devices, materials, methods and techniques disclosed in the above-mentioned incorporated applications and patents.

The articles disclosed herein may be formed through any suitable means. The various methods and techniques described above provide a number of ways to carry out the invention. Of course, it is to be understood that not necessarily all objectives or advantages described may be achieved in accordance with any particular embodiment described herein. Thus, for example, those skilled in the art will recognize that the methods may be performed in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other objectives or advantages as may be taught or suggested herein.

Furthermore, the skilled artisan will recognize the interchangeability of various features from different embodiments disclosed herein. Similarly, the various features and steps discussed above, as well as other known equivalents for each such feature or step, can be mixed and matched by one of ordinary skill in this art to perform methods in accordance with principles described herein. Additionally, the methods which are described and illustrated herein are not limited to the exact sequence of acts described, nor are they necessarily limited to the practice of all of the acts set forth. Other sequences of events or acts, or less than all of the events, or simultaneous occurrence of the events, may be utilized in practicing the embodiments of the invention.

Although the invention has been disclosed in the context of certain embodiments and examples, it will be understood by those skilled in the art that the invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses and obvious modifications and equivalents thereof. Accordingly, the invention is not intended to be limited by the specific disclosures of preferred embodiments herein.

What is claimed is:

1. An implantable device configured to be secured within an air passageway, the device comprising:
  - a distal portion comprising an anchor system and a longitudinal axis, the anchor system comprising at least one piercing tip and being configured to engage tissue of an air passageway wall;
  - a proximal portion; and
  - a flexible portion connecting the distal portion to the proximal portion, the flexible portion being configured such that the distal portion can articulate substantially with respect to the proximal portion such that the distal portion and the proximal portion are non-collinear along the longitudinal axis of the distal portion.
2. The device of claim 1, wherein the proximal portion has a larger diameter than the distal portion.
3. The device of claim 1, wherein the distal portion, the proximal portion, and the flexible portion are all formed in a single piece.
4. The device of claim 1, wherein the at least one piercing tip comprises a planar member configured to limit advancement of the at least one piercing tip into the tissue of the air passageway wall.
5. The device of claim 1, wherein the at least one piercing tip is atraumatic.
6. The device of claim 1, wherein the anchor system comprises a plurality of piercing tips extending radially outward relative to the longitudinal axis of the distal portion.
7. The device of claim 1, wherein the flexible portion is hollow.



## 13

8. The device of claim 1, wherein the flexible portion comprises a rigid rod portion.

9. The device of claim 8, wherein the rigid rod portion extends through an axial center of a helical spring.

10. The device of claim 1, wherein the flexible portion comprises a tube or cylindrical member having one or more slots.

11. The device of claim 1, wherein the flexible portion comprises a spring member extending in a longitudinal axial direction.

12. The device of claim 1, wherein the flexible portion comprises a flexible mesh.

13. The device of claim 1, wherein the proximal portion comprises a frame member.

14. The device of claim 13, wherein the frame member comprises one or more struts.

15. The device of claim 13, further comprising a membrane portion disposed over at least a portion of the frame member.

16. The device of claim 1, wherein the device is collapsible for containment within a delivery catheter.

17. The device of claim 1 further comprising an elongate member with a proximal end and a distal end, the elongate member being attached at its distal end to the proximal portion or the distal portion.

18. The device of claim 17, wherein the elongate member is configured to be engaged by a removal tool for repositioning or removal of the device.

19. The device of claim 17, wherein the elongate member comprises a knob at its proximal end.

20. A system for inserting a pulmonary device into an air passageway of a lung, the system comprising:

a catheter; and

a pulmonary device configured to be inserted into a distal end of the catheter, the pulmonary device comprising:

a proximal portion;

a distal portion comprising a longitudinal axis and at least one anchor configured to secure the pulmonary device within the air passageway, and

## 14

a connecting member coupling the proximal portion and the distal portion and allowing the longitudinal axis of the distal portion to be non-collinear with the proximal portion.

21. The system of claim 20, wherein the proximal portion comprises a frame member.

22. The system of claim 21, wherein the frame member comprises a plurality of struts.

23. The system of claim 22, wherein the plurality of struts extend in a longitudinal direction and form a bell or umbrella shape, and wherein the plurality of struts are connected to each other at a first distal end.

24. The system of claim 23, wherein the plurality of struts have a second proximal end curving inward toward the longitudinal axis.

25. The system of claim 21, wherein a membrane covers at least a portion of the frame member.

26. The system of claim 20, wherein the proximal portion comprises a proximal rod extending along a longitudinal axis of the proximal portion.

27. The system of claim 26, further comprising a removal tool configured to engage the proximal rod.

28. The system of claim 20, wherein the pulmonary device is in an at least partly collapsed configuration when inserted into the distal end of the catheter.

29. The system of claim 20, wherein the connecting member comprises a tube or cylindrical member with one or more slots.

30. The system of claim 20, wherein the connecting member comprises a spring.

31. The system of claim 20, wherein the connecting member comprises a mesh.

32. The system of claim 20, wherein the connecting member comprises a rigid rod connected to one or more pivot points or flexible portions.

33. The system of claim 32, wherein the pivot point or flexible portion comprises at least one ball and socket assembly.

34. The system of claim 32 further comprising a spring member arranged along an axis of the rigid rod.

\* \* \* \* \*